COMPARATIVE STUDY OF ENDOCERVICAL APPLICATION OF PGE_2 GEL COMBINED WITH EARLY INTRAVENOUS INFUSION OF OXYTOCIN AND OXYTOCIN ALONE FOR INDUCTION OF LABOUR AT TERM IN WOMEN WITH UNRIPE CERVIX

THESIS

FOR

MASTER OF SURGERY

(OBSTETRICS & GYNAECOLOGY)

BUNDELKHAND UNIVERSITY

JHANSI (U. P.)

1995 SUDHA GUPTA

C E R T I F I C A T E

This is to certify that the work entitled "COMPARATIVE STUDY OF ENDOCERVICAL APPLICATION OF PGE_2 GEL COMBINED WITH EARLY INTRAVENOUS INFUSION OF OXYTOCIN AND OXYTOCIN ALONE FOR INDUCTION OF LABOUR AT TERM IN WOMEN WITH UNRIPE CERVIX", which is being submitted as a thesis for M.S.(Obstetrics & Gynaecology) by Dr. Sudha Gupta, has been carried out under my direct supervision and guidance. The techniques embodied in the thesis were undertaken by the candidate herself. and observations recorded have been periodically checked and verified by me.

Date :-
22.11.94

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(GUIDE)

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She has put in the necessary stay in the department as per university regulations.

Dated :

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Sudha Gupta

(Sudha Gupta)

Date :-

22.11.94

C O N T E N T S

I N T R O D U C T I O N

INTRODUCTION

Women's specific health needs are intimately connected to their reproductive role. Safe motherhood concept aims at providing the support systems to ensure satisfactory outcome of labour for the mother and her unborn child.

Giving birth to a baby on one hand provides happiness to the mother and entire family but on the other hand it has always been darkened with pain, agony and fear of some mishap. For ages long there has been no solution for the problems of prolonged labour leading ultimately to great mortality and morbidity.

The process of parturition is a complex process involving the uterus, the cervix and the body system as a whole. In attempts to augment the labour process attention was primarily but mistakenly directed to only the uterus as the main contractile and propulsive forces for the foetus, while the cervix has been regarded as a passive, inferior part of the uterus which resulted in many unfortunate failures and subsequent problems.

Today, increased knowledge of the biochemistry and histology of the cervix indicates that this organ plays a much more active and prominent role in the delivery mechanism and it is a well known fact that success of induction depends to a large extent upon the consistency, compliance and anatomic configuration of the uterine cervix.

The process involving physically detectable softening, shortening and dilatation of cervix occurring before the onset of parturition is referred to as ripening or priming. The process of ripening has been suggested to occur over a period of time as short as 12 hours and as long as 6 to 8 weeks. The onset of labour, length of labour and success of induction of labour all depend on the degree of cervical ripeness. Induction of labour for medical and obstetric indications leads to a successful vaginal delivery in a high percentage of patients with ripe or easily inducible cervices. But on the other hand, induction of labour in a patient with an unripe cervix has always posed a formidable challenge to the clinician. Patients with firm closed and unripe cervices at the time of induction have a high incidence of failed induction(20-50%). (Bishop 1964 , Friedman, 1966). More maternal pyrexia, birth asphyxia, further, when vaginal delivery is achieved, these patients undergo prolonged labour, higher incidence of instrumental delivery and increased maternal and foetal morbidity (Turnbull, 1968).

However, in numerous circumstances such as when pregnancy is complicated by pre-eclampsia, essential hypertension, prolonged gestation, intrauterine growth retardation, intrauterine death, oligohydramnios, diabetes, suspected placental insufficiency, Rh sensitization, necessitate delivery, induction of labour is usually pursued, if immediate delivery is not eminent.

The ideal cervical priming agent is one that causes cervical change similar to that seen in the natural ripening process. It should not affect the uterine blood flow or the feetoplacental unit as many of the foetus involved are at high risk. It should neither affect the uterine, blood flow nor the foetoplacental unit nor maternal well being by causing extreme vomiting, diarrhoea, infection or discomfort. There should be no trauma to cervix and uterus which would affect the future pregnancies in a detrimental manner. The agent should be safe and practical to use and should not require complicated storage and preparation. The application should be acceptable to the patient and staff and cause no untoward complication. It should be economical.

A long list of mechanical, hormonal and medical methods have been tried over the years. Of all the priming agents local prosta-glandin gel has proved to be the most desirable priming agent. Prostaglandins, PGE_2 in particular is directly involved in the initiation of labour and cervical priming and is also produced endogenously.

The clinical response to oxytocin depends on the functional state of both the cervix and myometrium. It is a well known clinical experience that unripe cervix may resist forceful myometrial contractions produced by oxytocin. Patients with firm closed and unripe cervices at the time of induction have a high incidence of failed induction(20-50%) (Bishop, 1964 and Friedman, 1966). Further, when vaginal

delivery is achieved these patients undergo prolonged labour higher incidence of instrumental delivery and increased maternal and fetus mortality (Turnbull, 1968).

Intracervical PGE_2 gel can ripen the cervix, permitting subsequent induction by oxytocin infusion, without the risk of myometrial hyperstimulation (Ekman Wingerup and Ulmsten, 1983).

In patients with favourable cervical state oxytocin infusion continues to be an affective and safe drug for term labour induction. There is an increasing evidence suggesting the endogenous production of prostaglandin in the cervical tissue is an important factor in cervical ripening. PGE_2 has been administered vaginally, endocervically extra amniotically in viscous vehicle. Endocervical gel application offers an advantage of lower dose and lesser side effects.

Very few side effects with cervix prime gel are occasional nausea and vomiting or diarrhoea, uterine contraction abnormalities with hypertonic contractions and foetal distress.

Intravenous oxytocin is found to be associated with uterine hypertonus, foetal bradycardia and water retention, an increased incidence of neonatal jaundice.

Thus, a local application of PGE_2 adds to the natural process, when compared with vaginal application. The intracervical application has fewer side effects because of direct access to the target organ and lower systemic dose required.

In the present study undertaken at M.L.B. Medical College, Hospital, "Intracervical PGE_2 gel is used for enhancement of priming and induction of labour at term in patients with an unfavourable cervix followed by oxytocin infusion after 12 hours and comparative study was done with oxytocin alone.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Today it is well established that the uterine body and the uterine cervix have to be considered as two entities closely related but with different functions.

The normal human cervix is a collagenous structure, that undergoes a dramatic and probably unique metamorphosis. In the nonpregnant state, the cervix is involved in the facilitation of sperm transport, prevention of invasion by micro-organism from vagina and outflow of menstrual blood and uterine secretions. While during pregnancy, cervix acts as a rigid sphincter for preserving the growing foetus in the uterus and for maintenance of pregnancy. At term, it dilates rapidly and effaces for easy passage of foetus.

Structurally, human cervix possesses all the components to meet the diverse demands throughout the reproductive cycle. Cervical canal is listed by columnar epithelium beneath which there are numerous glands(secretory units) to produce the cervical mucus. The main body of the cervix consists of stroma, made primarily of connective tissue. Which predominantly has collagen. The basic molecule of collagen is tropocollagen which is oriented in parallel and staggered in such a way that they create typical light and dark bands under electron microscope.

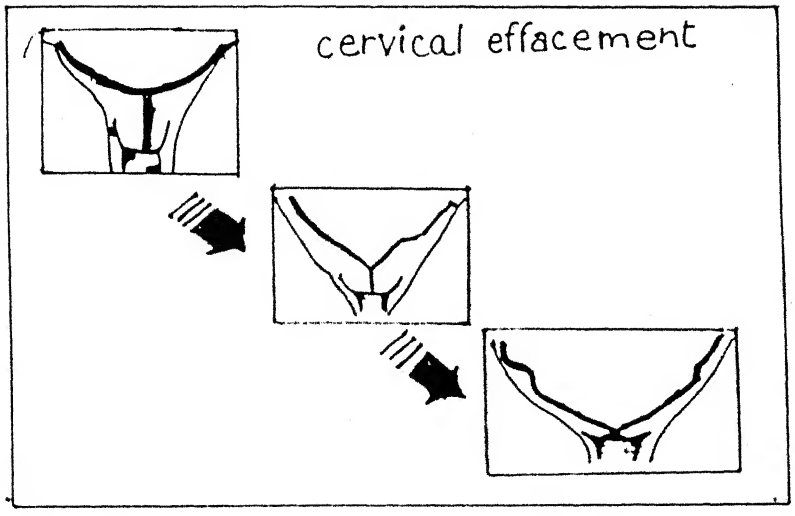
The cervical connective tissue at term shows widely scattered and dissociated collagen fibriles with

an increase in the ground substances when compared to the early pregnant or nonpregnant cervix(Danforth et al, 1960).

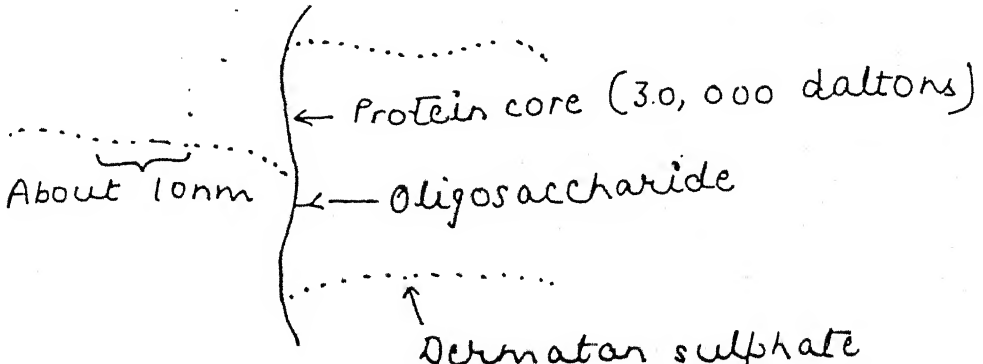
The collagen fibriles are embedded in a ground substabce containing large molecule structure proteoglycon complexes containing a variety of glycosaminoglycans(GAGS). Hyaburonic acid binds least strongly of the GAGs molecules and will act to de-estabilize the collagen fibriles while GAGs containing iduronic acid and dermatan sulphate bind strongly and promote tissue stability (Obrink, 1973). The GAG slide chains of the proteoglycan then interact with further collagen, molecules and with each other. This relationship is important in orienting the collagen fibriles and thus providing mechanical strength (Lindahl and Hoo, 1978; Golichowiski, 1980). The binding affinity of GAGs to collagen increases with increasing chain length and charge density.

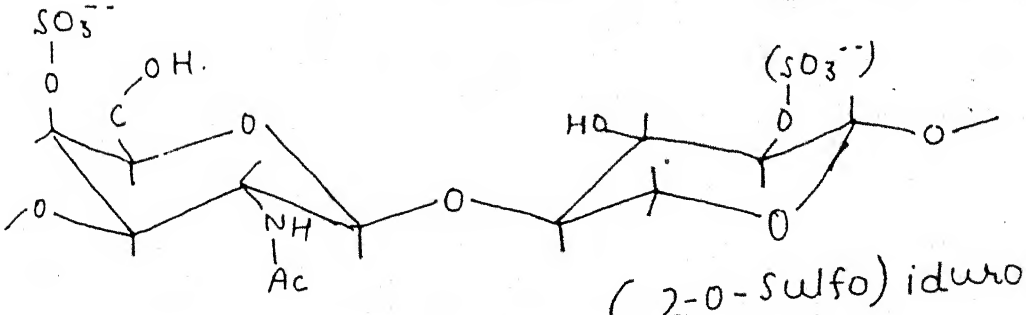
The non-pregnant cervix consists of 80% water which increases to around 86% during late pregnancy (Liggins, 1978). In view of the highly hydrophyllic property of the GAGs, these molecules may be important in determining the amount of tissue hydration, with increased hydration destabilizing the collagen fibriles and GAGs are produced by fibroblasts which constitute the major cellular component of the cervical connective tissue.

The collagen fibres are embedded in a ground substance containing large molecule structure proteoglycan complexes containing a variety of glycosaminoglycans(GAGs).



THE DERMATAN SULPHATE PROTEOGLYCAN & A GLYCOSAMINOGLYCAN





(2-O-Sulfo) iduronic acid

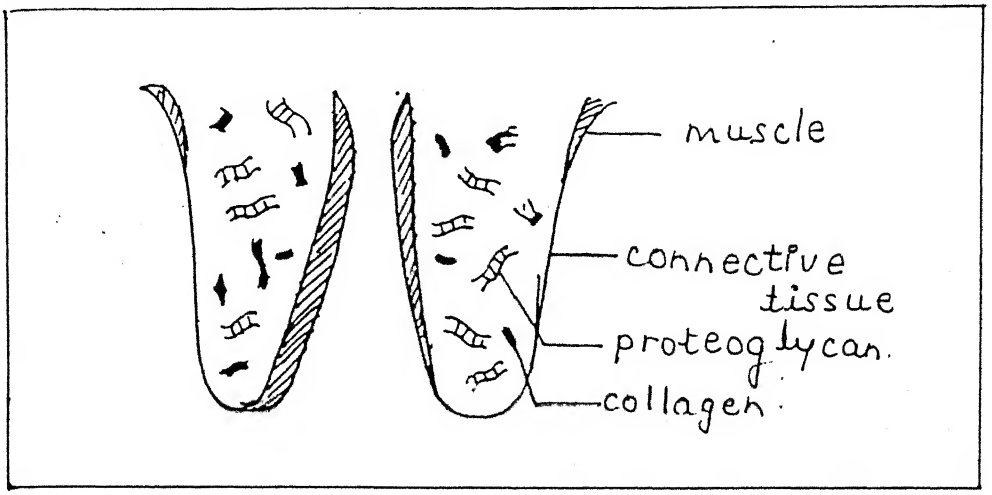
4-O-Sulfo-N-acetylgalactosamine.

the most abundant being chondroitin sulphate and epidermatan sulphate (Von Mailot et al, 1979; Uldberg et al, 1983). There is change in glycosaminoglycan and water content, a relative increase in hyaduronic acid and a relative decrease in chondroitin sulphate and dermatan sulphate (Von Mallot et al, 1979). Hyaluronic acid has substantial hydrophyllic properties influencing tissue hydration and thereby tissue tissue deformability causing an increased compliance. The increase in hyaluronic acid is due to breakdown of proteoglycan complexes by protease enzymes from the activated fibroblasts or leucocytes which infiltrate the connective tissue. The accumulation of hyaluronic acid and water between collagen fibres disperses them and increases distensability. A decrease in chondroitin sulphate concentration reduces the mechanical strength of the collagen fibriles and make them more prone to breakdown by proteolytic enzymes. The amount of soluble collagen in the tissue increases in parallel with the increased enzyme activities (Ito et al,1979; Uldberg et al, 1983).

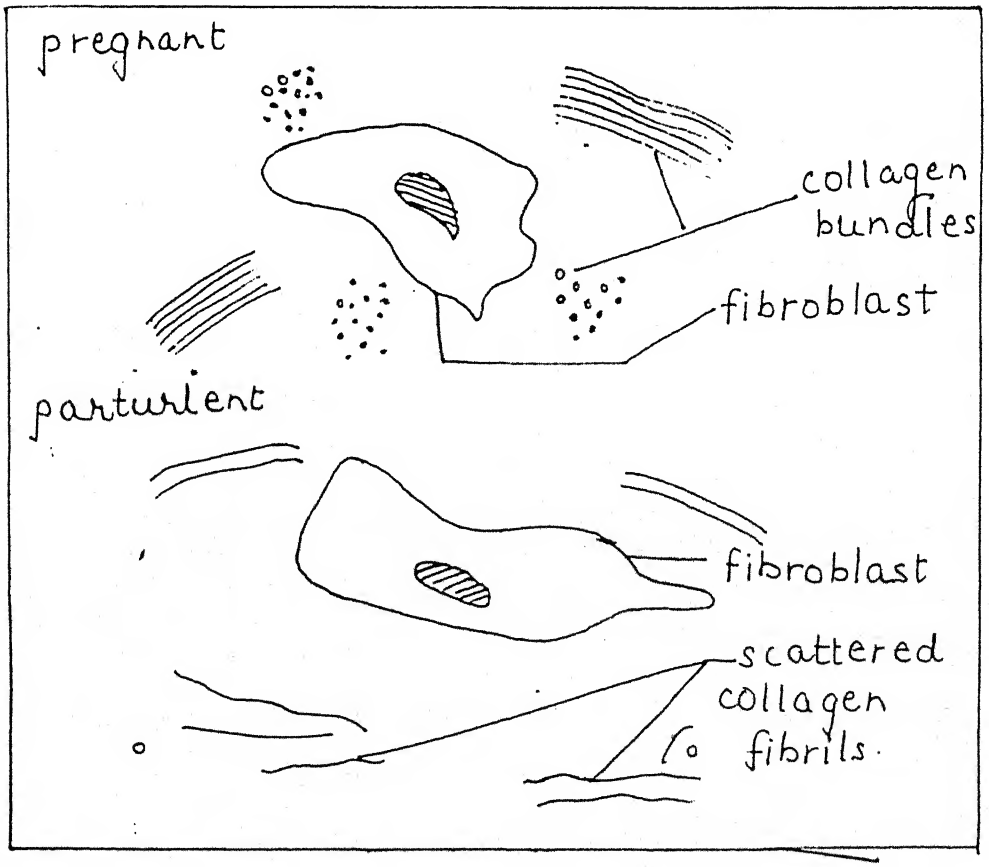
In addition to forming the ground substance of the tissue, proteoglycans invest collagen fibriles (Scott and Orford, 1981) with the protein ions attaching to the collagen.

Collagen is amenable to breakdown by only two enzymes, collagenase produced by fibroblasts and leucocytes and leucocytes elastase produced by macrophages, polymorphs

STRUCTURE OF THE HUMAN UTERINE CERVIX



STRUCTURAL CHANGES IN PRIMING.



and eosinophils. Elastase causes breakdown of elastin collagen and proteoglycans. The collagen fragments produced by these enzymes is further broken down by non-specific proteases such as neutral proteases and alkaline proteases. As the cervical collagen concentration decreases through pregnancy, the leucocyte elastase and collagenase activity increases (Uldberg et al, 1983).

Thus there is remodelling of collagen during pregnancy and parturition. The mature collagen with many cross links is broken down and is replaced with new collagen which has fewer cross links and can breakdown more rapidly during parturition.

Alongwith collagens and proteoglycans, a small amount of elastin is also present in the cervix. It is present as 20-30 micromole/l bands in a lamellar network forming a funnel like structure in the cervix as compared to the fibrillar elastin fibres in the uterine corpus (Lappert and Yu, 1990).

During the days to weeks before the onset of labour, the consistency of cervix ordinarily changes so that is becomes softer and more readily distensable. The cervix also begins to shorten (Effacement) and the endo-cervical canal widens (dilatation), the process of cervical ripening. The changes associated with cervical ripening include a reduced collagen concentration within the tissue, an increase in water content and change in GAG content.

FACTORS INFLUENCING CERVICAL RIPENING

It appears that estrogens, progesterones, relaxin, prostaglandins, leucotrienes and catabolins, all may be the mediators for the regulation of synthesis and catabolism of connective tissue in the human uterine cervix.

ESTROGENS

Previous action of estradiol is necessary in order that progesterone and relaxin may later act upon the cervix. There is an increment of physiological phenomenon connected with the ripening of cervix (edema, increased vascularity and softening)(Pinto et al, 1965).

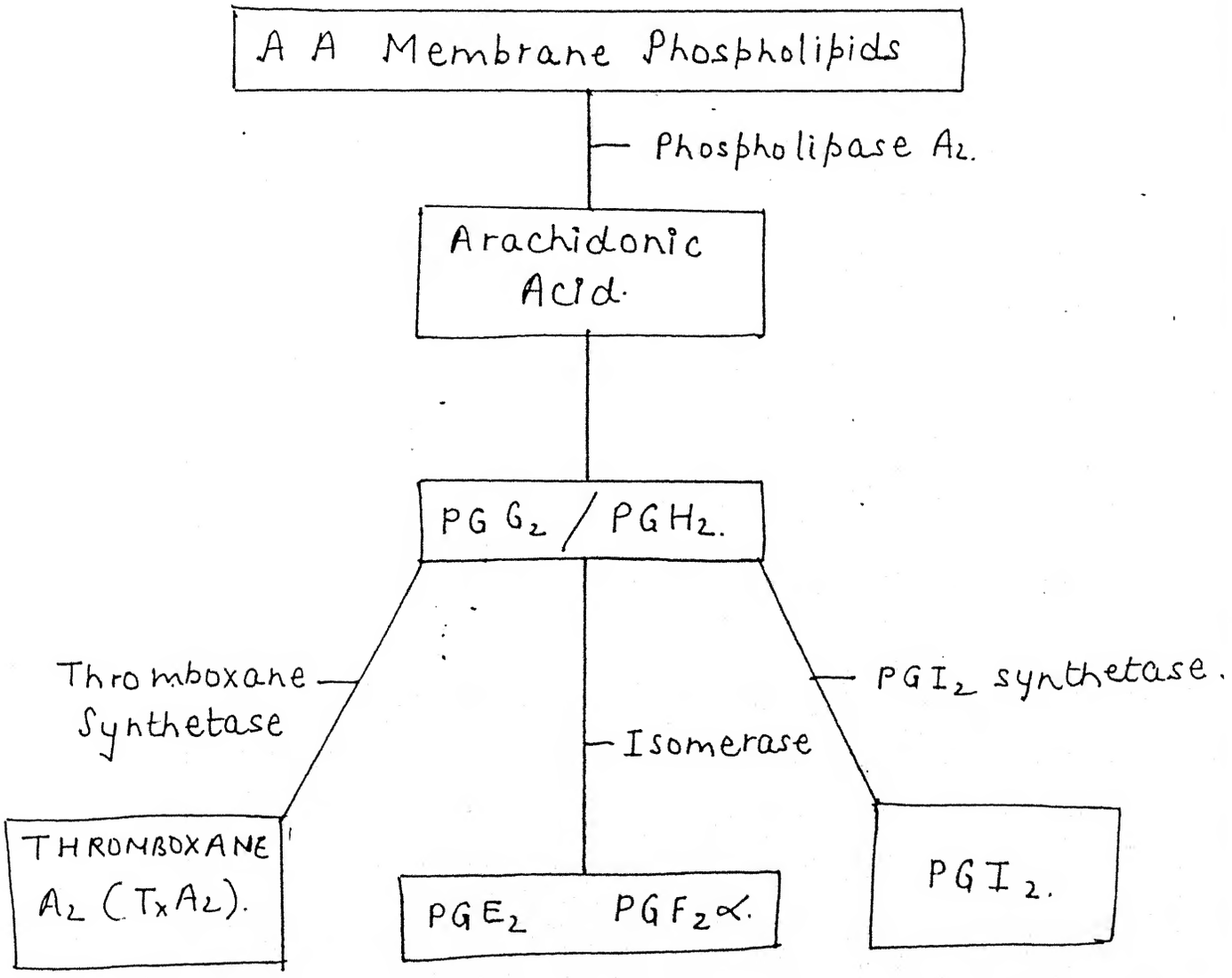
Estradiol has moderate oxytocic action upon the pregnant uterus at term and has an accelerating effect on the physiological phenomenon of cervical ripening (Pinto et al, 1965).

Estrogens promote cervical ripening probably by upregulation of collagenase and other proteolytic enzymes Mochizuki and Tojo, 1980). They also seem to contribute to the induction of phospholipase activity thereby increasing local production of PGE_2. Estradiol might be responsible for the influx of protease producing leucocytes which could induce ripening and which could not be evident in vitro.

PROSTAGLANDINS

Human semen was first noted to produce uterine contractions by Kurzok and Lieb (1930) (Pickles, 1967).

THE ARACHIDONIC ACID PATHWAY FOR PROSTAGLANDIN(PG) AND LEUKOTRIENE PRODUCTION.



AA - Arachidonic acid

Subsequently the active ingredients were identified as prostaglandins.

Term prostaglandins was coined by Von Euler (1935). Prostaglandins are now knwon to exist in virtually every mammalian tissue and have important physiologic and pharmacologic activities. Prostaglandins are not stored in tissues but are formed from precursor fatty acids(diromogamma linolenic acid, arachidonic acid, eicosapentaroic acid) which are freed from covalent bonding in phospholipids, triglycerides, cholesterol esters and other fatty acid compounds.

Depending on the precursor fatty acid prostaglandins of the 1, 2 and 3 double bond series are formed . In most physiologic systems, prostaglandins of the 2-series (PGF_2 and PGE_2) formed from arachidonic acid are most important.

Prostaglandins are naturally occurring substances of family of polyunsaturated 20 carbon fatty acids containing a cyclopentase ring and two aliphatic side chains chemically derivative of hypothetical prostanoic acid. Prostaglandins are divided into groups A, B, C, D, E, F, G, H and I, which are subdivided according to degree of unsaturation of side chains and a suffix denoting the number of double bond (e.g. PGE_1, PGE_2, PGE_3) when stereoisomerism exists its nature is shown by additional subscripts alpha or beta (PGF_2 alpha and PGF_2 beta). Only alpha isomer occurs naturally .

Prostaglandins are synthesized in vivo by cyclization of the centre of the carbon chain of 20-C(eicosaroic) polyunsaturated fatty acids, (e.g. arachidonic acid) to form a cyclopentase ring.

Arachidonic acid is a common constituent of phospholipid present commonly at C_2 position from which it is liberated by acylhydrolase phospholipase A_2. By the incorporation of two molecules of oxygen, arachidonic acid is converted to a highly unstable endoperoxide PGE_2, which then looses an oxygen radical to become PGH_2 from which all prostaglandins of the 2-series and thromboxane A_2 (TXA_2) are formed. Cyclooxygenase, the enzyme catalyzing the formation of PGG_2 from arachidonic acid. Mainly present in cells in an inactive form that is rapidly activated by substrate. The rate of prostaglandin synthesis is controlled by the rate of release of arachidonic acid from stores rather than by activity of cyclo-oxygenase (Mc Donald et al, 1978).

SITES OF SYNTHESIS OF PROSTAGLANDINS IN UTERUS

It is found that uterine epithelium is the major source of PGF_2 alpha whreas the myometrium produces predominantly prostacyclin PGI_2 and a good amount of PGF_2 alpha. The endometrium metabolizes the arachidonic acid formed within endometrial cells and that from neighbouring tissues as amnion and chorion.

The main prostaglandins produced by the cervix are (PGE_2, PGI_2 and to lesser extent PGF_2 alpha. Their production

increases towards term and peaks during labour. Amniotic fluid concentration of PGE_2 and PGF_2 alpha also increases.

CONTROL OF PG SYNTHESIS

Effect of rising levels of cortisol in the fetal circulation is to divert progesterone synthesis towards estrogen synthesis, thus causing less progesterones and more estrogen to be secreted. Progesterone has a complex action on PG synthesis. On one hand it enhances the capacity to synthesize and on the other hand, it inhibits secretion.

Estrogen stimulates PG synthesis particularly from tissue previously exposed to progesterone. Thus the marked increase in estrogen progesterone ratio at term is a powerful stimulus for PG release. PGs act possibly by two ways :

1. They induce collagen breakdown.
2. They alter collagen binding and tissue hydration by altering GAG/proteoglycan composition.

Prostaglandin E_2 has double effect.

1. Regulate the C-AMP in the target cell.
2. Augment the activity of hyaluronic acid synthetase enzyme.

The increase in GAG production by PGs is by the increased hyaluronic acid synthesis within the fibroblasts under the influence of hyaluronic acid synthetase enzyme (Murota et al, 1977).

PGE_2 influences the cervical fibroblast production

of collagen and GAG. The production of these two substances is inversely related so that when collagen synthesis is reduced, an increase in GAG production occurs (Norstorm, 1984; Normstorm et al, 1985).

Secondly PGE_2 may induce proteolytic breakdown of proteoglycan complexes which causes increase in free hyaluronic acid content.

PGE_2 also causes release of stored collagenase/ elastase from leukocytes. After treatment with PGE_2 these cells (leukocytes and fibroblasts) are enriched with vesicles localised close to the plasma membrane. They also contain long dendrite arms shortening the diffusion distance from the cell to any point in the tissue. Thus PGE_2 mediated cervical ripening easily explained by changes in GAG content which disperses and destabilize the collagen fibriles and increases tissue compliance.

RELAXIN

Relaxin is a polypeptide hormone similar to insulin, produced in the human corpus lutea, decidua and corion (Weis et al, 1977; Maclennan et al, 1980). Human fibroblasts exhibit relaxin receptors and relaxin has a mutagenic effect on fibroblasts (McMurty et al, 1980). It stimulates cervical fibroblasts to release proteases which destroy the link proteins that hold the collagen framework together. This interaction may be dependent upon relaxin; interaction with estrogen and progesterone. Histologic

changes co-incident with cervical ripening induced by relaxin are indistinguishable from those induced by application of prostaglandins (Maclennen, 1980). Relaxin has been shown to have some effect on cervical ripening on women (Maclennen, 1981), and has been reported to increase collagenase activity. During pregnancy it seems to play a role in connective tissue remodelling at several anatomical sites (Evans et al, 1983).

OXYTOCIN

Oxytocin is secreted from both the maternal and fetal neurohypophysis during spontaneous labour.

Oxytocin is found in increasing concentration in amniotic fluid towards term (Dawood et al, 1978).

Oxytocin stimulates prostaglandins production in human uterine tissues. The decidua and amnion are the sites for the stimulatory action of oxytocin and not the myometrium, the classic target organ for oxytocin action (Fuchs et al, 1981).

There is high concentration of oxytocin receptors in the decidua at term. Myometrium also has a high oxytocin receptor concentration at term (Fuchs et al, 1981) but in the myometrium these receptors mediate only the contractile effects of this neurohypophyseal peptide (Fuchs et al,1981), whereas in the decidua they serve a different function concerned with the biosynthesis of prostaglandins.

PROGESTERONE

It increases synthesis of prostaglandins in the cells but inhibits its release. Thus progesterone is an important physiological inhibitor of the ripening process in vivo by inhibiting neutrophil influx and activation (Jeffre and Koob, 1980). This possibility is supported by the ripening effects of arti-progestin on the cervix prior to termination of pregnancy (Gupta and Johnson, 1990; Radstead et al, 1990).

Progesterone seems to exert its influence on the myometrium by inhibiting sodium flux through the myometrium membrane and by raising the resting membrane potential

EVALUATION OF THE CERVIX

A cervix that is unprepared and requires intervention and a cervix in which ripening process has already occurred must be differentiated before going in for induction of labour. The most readily used methods to make this assessment depend upon physical characteristics of the cervix. Bishop (1964) was the first to attempt to quantify the physical examination of the cervix by introducing a numeric scoring system. With their evaluation method one could predict an optimal time to begin induction as well as how long it would take a patient with a given score to go into spontaneous labour. When a high score is present, it is assumed that changes constituting cervical ripening have occurred and no further attempts to ripen

the cervix are needed (Bishop, 1964).

This was evaluated further by Friedman et al (1966) using the Bishop scoring system. These authors confirmed that the success or failure of induction correlates directly with the cervical score. With a score of 9 or more no one had failed induction. There was a 5 percent failure rate with a score of 6 to 8 and 20% failure of induction rate if the patient had a cervical score of 5 or less.

These authors also demonstrated that the pre-labour cervical score is directly related to the length of latent phase. As the pelvic score increases, while all other periods of labour are shortened the change is most apparent in the latent phase. The variation in the lengths of the latent phase in normal labour represent the variations of cervical preparedness.

Finally, of all the Bishop scoring parameters, the authors found dilatations to weight the most important and position of the cervix to weigh the least in determining the predictability of the score.

Calder et al (1977) and Wingerup et al (1978) have also published numeric rating system to evaluate the inducibility of the cervix.

Numerical scoring systems used to evaluate the inducibility of the cervix are given below.

Factor	Score			
	0	1	2	3
A. Bishop (1964)				
Dilatation (cm)	0	1-2	3-4	5-6
Effacement (%)	0-30	40-50	60-70	780
Station	-3	-2	-1; 0	+1, +2
Consistency	Firm	Medium	Soft	-
Position	Posterior	Mid	Anterior	-

No induction failure with pelvic score, more than or equal to 9. 20% induction failure rate when pelvic score less than or equal to 4.

0-5 unfavourable.

6-13 favourable.

Factor	Score			
	0	1	2	3
B. Calder et al (1977).				
Dilatation (cm)	< 1	1-2	2-4	> 4
Length (cm)	> 4	2-4	1-2	< 1
Consistency	Firm	Average	soft	-
Position	Posterior	Mid	Anterior	-
Station of head from ischial spines (cm)	3 & above	2 and above	0-1; 0	+1, +2

Cervical score of 3 or less has more complicated inductions including longer labours and increased rates of pyrexia and caesarean sections.

Factor	Score			
	0	1	2	3
C. Wingerup (1979)				
Dilatation (cm)	<0.5	0.5-1.5	>1.5	-
Effacement (%)	None	<50	> 50	-
Station of fetal head	> or in pelvic inlet	> spines	AT/OR below spines	-
Consistency	Firm	Medium	Soft	-
Position	Posterior	Mid	Anterior	-

A pelvic score of 0-5 indicates that the cervix is infavourable for induction, while a score of 6-10 indicates that it is favourable.

From the above account it is clear that cervical ripening greatly facilitates labour and ultimately influences the prospectives for a vaginal delivery, specially in nulliparous patients. Failure of cervix to ripen significantly increases the chance of both post dated delivery and caesarean section, particularly when induction of labour is considered necessary. Under these circumstances, if measures are not taken to improve the cervical status before induction, oxytocin infusion alone may be relatively ineffective, resulting in prolonged induction, induction failure, an unacceptable rate of caesarean section (>40%), prolonged hospital stay, increased medical costs and overall increase in maternal and fetal morbidity.

In search of an ideal priming agent, various agents and methods have been used over the years, which are broadly classified as mechanical and medical.

A. Mechanical

1. Manual dilatation and stripping membranes.
2. Balloon catheters and self retaining Foley's catheters.
3. Hygroscopic
   Laminaria tents
   Lamical
   Dilapan.

B. Medical

1. Oxytocin
2. Oestrogen
3. Prostaglandins
4. Relaxin

MANUAL DILATATION AND STRIPPING MEMBRANE

Manual dilatation and insertion of foreign bodies into the endocervix and above the internal Os are the oldest methods available for ripening the cervix described in the writings of Hippocrates, serial digital dilatation of the unripped cervix is not done because of patient's noncompliance but stripping or sweeping of the membranes is one of the most widely used mechanical methods for promoting cervical ripening and inducing labour. This is done by insinuating one or two fingers in the extra-amniotic space above the internal Os and then sweeping the fingers 360 degrees. Thereby separating the membranes from

the lower uterine segment . It is successful when pelvic score is good. With completely unripe cervix it fails and is inconsistent in its efficacy.

Excitation of the neural autonomic reflex and the release of oxytocin from the posterior pituitary may contribute (Fuchs et al, 1965).

The cervical ripening occurs because of local PG release, either PGF_2 from the chorio-amniotic membranes and adjacent decidua or PGE_2 from within cervix itself(Liggins et al, 1978 and Seilers et al, 1980). Direct effects of tissue stretching and disruption and the introduction of localized infection are the factor which initiate PG release.

BALLOON CATHETERS AND HYGROSCOPIC CERVICAL DILATORS

When the cervix is extremely unfavourable these are more advantageous for cervical ripening as they cause more gradual cervical dilatation and are associated with minimal patient discomfort. In addition, there is an increase in uterine activity which augments the local effects of the cervix and facilitates induction of labour with oxytocin.

Historically, various balloon catheters have been used to induce cervical ripening since the mid 1800's (Delee et al, 1966).

More acceptable, alternative method of cervical dilatation is the use of hygroscopic catheters (Rosenberg, 1980; Blue monthal et al, 1990).

In experienced hands they are a safe and reliable

method (Manabe et al, 1981). Though effective, the balloon catheters are cumbersome, archaic and aesthetically sub-optimal.

Several hygroscopic dilators are available. Laminaria tents made from dessicated stems of cold water sea weed (Laminaria Digitate, Japonica) available in various sizes, when placed in the endocervix for 6-12 hours, increase in diameter 3-4 fold without increase in length occurs. They appear to act primarily by expansive radical force to the cervical canal. But there is other mechanism which is not clear. Being natural products they have some disadvantages as it is difficult to control their content, and sterilization. Therefore, several synthetic hygroscopic dilators are introduced in which quality control can be done and they are equally effective safe and easy to use. Lamicel, a polyvinyl alcohol polymer sponge, impregnated with 450 mg of magnesium sulphate available as a sterile compressed, rigid cylinder 77.75 mm long and either 3 or 5 mm in diameter.

DILAPEN

Made from a stable, non tonic, hydrophyllic polymer of polyacrylonitrite, available as sterile, rigid rods in various dimensions (4 x 65 mm; 4 x 55 mm and 3 x 55 mm) is safe and efficacious cervical dilator (Blumenthal et al, 1990).

MEDICAL METHODS

Oxytocin

A new milestone in the world of obstetric was reached when a posterior pituitary polypeptide known as oxytocin discovered by Sir Henry Dale was first used for induction of labour by Theobald (1956, 1959) and known as Pit drip.

It has been observed that in patients with an unripe cervix, infusion of oxytocin often fails to induce labour. In addition, this procedure does not prime the cervix (Wingerup et al, 1978).

Oxytocin for induction of labour in the presence of unripe cervix has led to a caesarean section rate for failed induction of approximately 50% (Prins et al, 1983; Shepherd et al, 1983).

Estrogens

Pinto et al (1965) described the oxytocin effect of high dose intravenous estradiol 17, as well as favourable effect on the cervical score.

Gordon and Calder (1977) concluded that local estradiol application was efficacious in priming and useful when placental function is suspected. It has been theorized that estrogens act on the cervix indirectly via local stimulation of PG synthesis.

Tromens et al (1981) found that a local estradiol vaginal gel in cervical priming was associated with a significant absence of uterine activity.

Prostaglandins

Labour induction with prostaglandins was first reported by Karim et al (1968) using PGE_2 and F_2 alpha given by various routes have confirmed their value as oxytocic drugs for labour induction. Since then many trials (using various systemic and topical formulations) have documented the efficacy of PGE_2 in pregnancy termination, cervical ripening and labour induction. Numerous controlled and uncontrolled clinical trials were undertaken.

Using an intravenous infusions, Embrey and Karim (1968) found PGE_2 to be 5-10 times in inducing term labour.

In patients with a favourable cervical state prostaglandins given intravenously or orally have not been found superior to oxytocin. Moreover, systemic administration of prostaglandins has been associated with considerable number of side effects, specially of GIT and also as inflammation at the site of infusion (Graff et al,1971). But in patients with unfavourable cervices, at term several investigators have found prostaglandins superior to oxytocin in inducing labour (Lindmark et al, 1975; Embrey et al, 1985). Even small doses of PGE_2 applied locally can provide significant improvement in cervical Bishop Scores, independent of uterine activity and with few systemic side effects (Calder et al, 1977; Bernstein et al, 1987).

These findings and reports from other clinical investigators suggest that PGE_2, in contrast to oxytocin and PGF_2 alpha may have a local priming effects on the

cervix. The results from the experience in vivo and in vitro in animals and in vitro studies in human cervical tissue by several investigators are also in accordance with these findings (Najakz et al, 1977).

Since PGs are categorised as locally acting hormones (Keirse et al, 1978) they should be administered preferably as close to the target organs as possible.

LOCAL APPLICATION OF PGs

Various routes are :-

1. Extra amniotic route
2. Intravaginal route
3. Intracervical route

The ideal preparation for cervical ripening would produce a satisfactory effect on the cervix while not stimulating myometrial activity.

As the overall goal of such intervention is to induce labour, myometrial activity may not be a serious objection, however, myometrial activity in advance of a complaint cervix will result in increased stress for mother and fetus which may be particularly problematical in in inductions where the fetus is compromised for example by intrauterine growth retardation.

The Extra amniotic Route

This was first to be studied by Calder and Embrey (1973). It involved transcervical passage of a foley's catheter where, it was retained in the extra - amniotic space by the inflated catheter balloon. PGE_2

in the dose of 400-500 microgram was then applied extra-amniotically, usually in a viscous gel such as tylose. The technique is valuable in the most unripe and difficult cases (Stewart et al, 1983). A number of controlled clinical trials (Calder, 1986) have shown a significant reduction in the induction delivery interval, caesarean section rate, maternal pyrexia rate, and incidence of babies born with low APGAR scores in women subsequently induced with amniotomy and intravenous oxytocin. The disadvantage of this technique is the invasiveness with a theoretical risk of infection and possibility of bleeding into the chorio-decidual space which could lead to uterine hypertonus due to rapid uptake of the PG. Patients may find the placement disagreable.

Intracervical Route

Calder et al (1977) presented the first promising results with the use of PGE_2 to hasten the ripening of an unfavourable cervix in pregnant women prior to induction of labour.

Follwing the studies by Ulmsten in Sweden (Ulmsten, 1979; Ulmsten et al, 1979), endocervical application of PGE_2 has become increasingly popular.

A variety of vehicles have been employed but the most commonly used ones are the triactin based gel marketed as prepedil (Upjohn) and the starch based gel developed by Ulmsten's group and marketed in Europe as cerviprost (Organon). The dose administered is 0.5 mg with each

preparation.

The procedure is less invasive than the extra-amniotic space. It requires skilful placement of the gel accurately in the canal avoiding placement into the extra-amniotic space as well as leakage from the external Os.

Suspected side effects could be uterine hypertonicity, fetal heart rate variability and decelerations, incidence of fetal distress, nausea, vomiting, fever, peripartum infection, but they are very less.

Ulmsten et al (1983) carried out a study of endocervical application of PGE_2 gel combined with early intravenous infusion of oxytocin for induction of term labour in women with unripe cervix. and found favourable results.

Potentials benefits include fewer serial inductions, fewer failed inductions, fewer inpatient days, lower medical costs, better timing of delivery, lower maternal and fetal morbidity and a shorter interval to decision regarding the need for a caesarean section.

Intravaginal Route

Successful cervical ripening can also be achieved in majority of patients with vaginal preparations in the form of tablets or gel.

A much larger dose is required than that used extra-amniotically or endocervically and repeated applications may be required (Stewart et al, 1983; Greer and Calder, 1984).

Disadvantage being side effects due to greater dose and lesser efficacy(Ekman et al, 1983). Sophisticated hydrogel polymers (Embrey and Mackenzie, 1985) allowing slow sustained release of PGE_2 have a major role. being easy to insert avoiding the more invasive techniques and avoiding the need for repeated application.

Relaxin

Several clinical trials conducted during the 1980, using purified porcine relaxin demonstrated its efficacy in promoting both pre-induction cervical ripening and labour in near term patients (Maclennan et al, 1985). Doses of 2 mg of relaxin in tylose gel administered as a single application either vaginally or intracervically promoted cervical ripening in 80% and labour in approximately one third of patients over 12 hour period.

The mean length of labour was significantly shorter and required less analgesic medicine with no significant maternal or foetal morbidity. Human relaxin has become available recently and clinical trials are underway in Australia (Maclennan, 1991).

MATERIAL AND METHODS

MATERIAL AND METHODS

The study was performed in 200 cases admitted in wards of department of Obstetrics and Gynaecology, M.L.B. Medical College, Hospital, Jhansi in the year 1993-94. Induction of labour with PGE_2 gel (Cerviprime) followed by intravenous oxytocin was carried out in 100 cases and results were compared with similar number of cases induced with intravenous oxytocin alone.

After interrogation with regard to name, age, parity and address detailed menstrual and obstetric history was taken in each case.

Complete general and systemic examination and complete obstetric examination with special reference to the size of the uterus, gestational age of the foetus, lie and presentation of the foetus was done and FHS was recorded in every case. Pervaginal examination was done to note the Bishop cervical score, to assess the pelvis and to confirm the integrity of membranes.

All patients had indication for induction of labour, and fulfilled the inclusion criteria for the study.

100 patients were given intracervical cerviprime (PGE_2) gel, 0.5 mg.

CERVIPRIME (PROSTAGLANDINS E_2 GEL)

PGE_2 gel for endocervical application is supplied in the form of triacetin based gel containing 0.5 mg of

PGE_2 or dinoprostone marketed under the brand of cerviprime made available by Astra-IDL Limited Bangalore. It comes in prefilled sterile ready to use syringe. The syringe comprises of three components, the barrel, the plunger, the catheter. In package, the plunger is attached to the nozzle of the syringe. The entire assembly is packed sterile in a blister pack.

Before administration of the drug the syringe is assembled as follows :

1. The plunger is removed from the nozzle of the syringe.
2. The catheter packed separately is attached to the nozzle.
3. Pushing the plunger would expel the gel through the catheter.

METABOLISM AND EXCRETION

Dinoprostone is one of the naturally occurring prostaglandin, produced mainly in the cervical tissue. It does not get stored or accumulated in the cervical tissue. Dinoprostone is removed through the oxidative pathways that give rise to metabolites which are excreted mainly in urine.

DRUG INTERACTIONS

Prostaglandins potentiate the action of oxytocin therefore oxytocin if required for induction of labour, should be used once the process of cervical ripening has begun, non-steroidal anti inflammatory drugs (NSAIDS) may

have effect on the action of PGE_2 hence to be used with caution.

STORAGE AND SHELF LIFE

It should be stored in the refrigerator at 2-8°C. It has a shelf life of 2 years from the date of manufacture. The contents of the syringe and the remaining gel if any, should be discarded after use.

PATIENT SELECTION CRITERIA

Antenatal patients at term (36-42 weeks) having a single fetus in cephalic presentation and vertex as the presenting part, were recruited for study if they fulfil the following inclusion criteria.

1. Gestational age of more than 36 weeks.
2. Bishop score of 5 or less than 5.
3. No contraindication for vaginal delivery like CPD, contracted pelvis.
4. No contraindications for prostaglandin.
5. Patient was not in labour.
6. Intact membranes.
7. Labour induction indicated for one or more of the following medical/obstetric reasons :-
   a. Post term/post dated pregnancy.
   b. Pregnancy induced hypertension/toxemia.
   c. Chronic hypertension.
   d. Intrauterine foetal death.

e. Oligohydramnios.

f. Intrauterine growth retardation.

g. Diabetes.

h. Rh iso-immunization.

CONTRAINDICATIONS

1. Hypersensitivity to prostaglandin.
2. Previous caesarean section or major uterine surgery.
3. Cephalo-pelvic disproportion.
4. Pre-existing foetal distress.
5. Grand multipara.
6. History of difficult or traumatic labour.
7. Ruptured membranes.
8. Patients with non-existing vertex presentation.
9. Vaginal bleeding.
10. History of asthma and epilepsy.

DRUG ADMINISTRATION

After evacuation of the bladder, the patient lies supine and kept in the lithotomy position. Under full aseptic techniques, the cervix is visualized using a speculum. The polythene catheter provided with the syringe is fitted to the nozzle is inserted through external cervical os into the cervical canal until the internal os is felt. The tip of the catheter is then withdrawn slightly. The contents of the syringe, the gel is slowly injected while withdrawing the catheter so as to fill the cervical canal. Care should be taken to avoid

spilling of the gel into the extra-amniotic space or into the vaginal canal. No attempt should be made to expel the gel remaining in the catheter. The patient should be asked to remain supine for atleast 30 minutes after gel instillation.

PRECAUTIONS

Certain precautions should be exercised while using cerviprime gel for ripening of cervix.

1. Should be used only in a well equipped obstetric hospital.
2. Care should be taken in patients with raised intraocular pressure.
3. To avoid side effects, care should be taken to ensure that the application is endocervical.
4. The uterine activity, foetal distress, cervical dilatation and effacement should be carefully monitored to detect hypertonic myometrial contractions and fetal distress.

ADVERSE REACTIONS

1. Occasional nausea, vomiting, and diarrhoea.
2. Intrapartum fetal heart rate change.
3. Uterine contractile abnormalities with or without fetal distress.

OVERDOSAGE

Applied in doses of 0.5 mg can cause hypertonic uterine contractions if gel is applied incorrectly and if

it spreads into the extra-amniotic space. If hypertonic uterine contractions are sustained possibility of uterine rupture should be considered. Beta agents like terbutaline can be used to relax the myometrium.

ONSET OF ACTION

Changes in the cervix start in about 5 hours from the time of gel application and completed in 12 hours to 24 hours.

PARAMETERS TO BE ASSESSED

Monitering of patient during labour and two hours postpartum for pulse, blood pressure, temperature, foetal heart sound, induction priming interval, induction delivery interval, uterine contraction pattern, mode of delivery, postpartum blood loss was done. Birth weight was taken and APGAR score of baby at birth and at 5 minutes was assessed.

After 6 hours of gel applications, cervical score was assessed. If labour did not ensue by reassessment at 12 hours, a second score was assigned and oxytocin induction was commenced with 0.5 unit syntocinon in 500 ml in 5% dextrose at drip rate of 8 drops/minute in escalating dose according to uterine sensitivity. Bishop scoring was done during labour.

INTRAVENOUS OXYTOCIN GROUP

In the control group, induction of labour was done by intravenous oxytocin that is syntocinon drip. To start with 0.5 unit syntocinon in 500 ml of 5% dextrose at drip rate of 8 drops/minute in escalating dose according to uterine sensitivity was given.

Criteria for Successful Induction

1. Initiation of labour within 24 hours of application.
2. Not jeopardizing the foetus.
3. Foetus should be delivered vaginally.

AIMS OF STUDY

1. To find an improved method for induction of labour with unripe cervix.

2. To find out the efficacy and safety of PGE_2 gel (endocervical application).

3. To study the effect of PGE_2 gel on ripening of cervix.

4. Comparative study of endocervical application of PGE_2 gel and intravenous oxytocin for induction of labour.

O B S E R V A T I O N S

OBSERVATIONS

The present study was carried out at M.L.B. Medical College, Hospital Jhansi for evaluating the efficacy of intracervical cerviprime PGE_2 gel (Cerviprime) for cervical priming and induction of labour in patients at term with unfavourable cervices and comparison was done with intravenous oxytocin for the same.

In this study, total 200 antenatal women were registered. All being at term or post term, gestational age was determined by LMP or ultrasonography. On pelvic examination, all of them had unfavourable Bishop Cervical score (0-5).

Cerviprime PGE_2 gel was instilled in subjects of group A (Study group) intracervically and subsequent effect on Bishop score and progress of labour was noted at 6, 12 and 24 hours after instillation. In cases where uterine contractions were not good, labour was augmented by intravenous oxytocin infusion after 12 hours.

Another group B (Control group) comprised of 100 women matched with study group for age, parity, gestational age, indications for induction and Bishop Cervical score in the range of 0-5. They were induced with intravenous oxytocin infusion. Progress of labour was studied and comparison was done with the study group for mean Bishop score at 0, 6, 12 and 24 hours duration of labour, mode of delivery, maternal and neonatal complications and

5 minutes APGAR score.

The study was carried out from April, 1993 to June, 1994. Various observations and results are tabulated as below.

TABLE I : Distribution of cases according to their age.

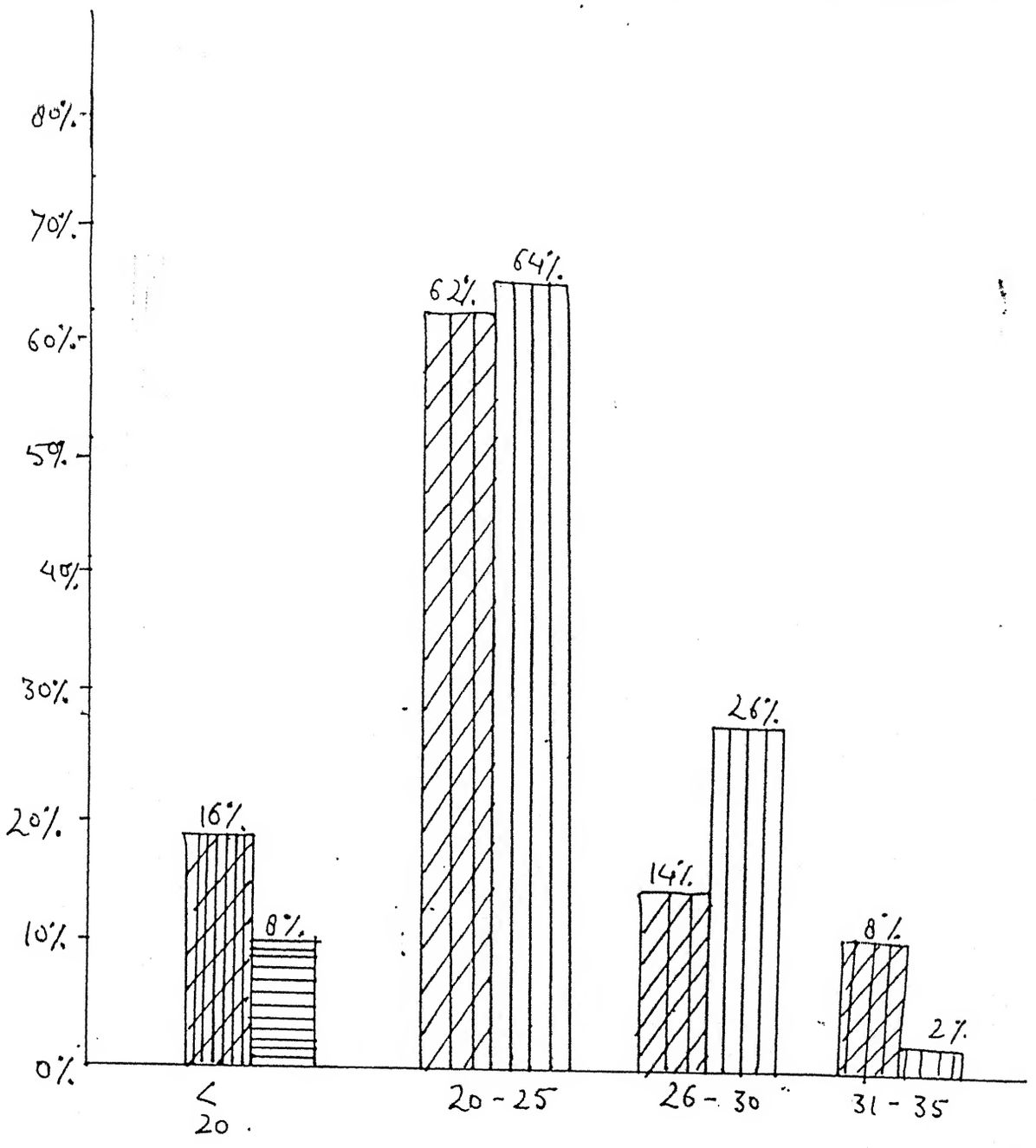
Age group (years)	Group A		Group B	
	No.	Percentage	No.	Percentage
<20	16	16.00	8	8.00
20 - 25	62	62.00	64	64.00
26 - 30	14	14.00	26	26.00
30 - 35	8	8.00	2	2.00
TOTAL	100	100.0	100	100.00

Maximum 62(62%) and 64(64%) cases in study and control group respectively were from 21-25 years of age.

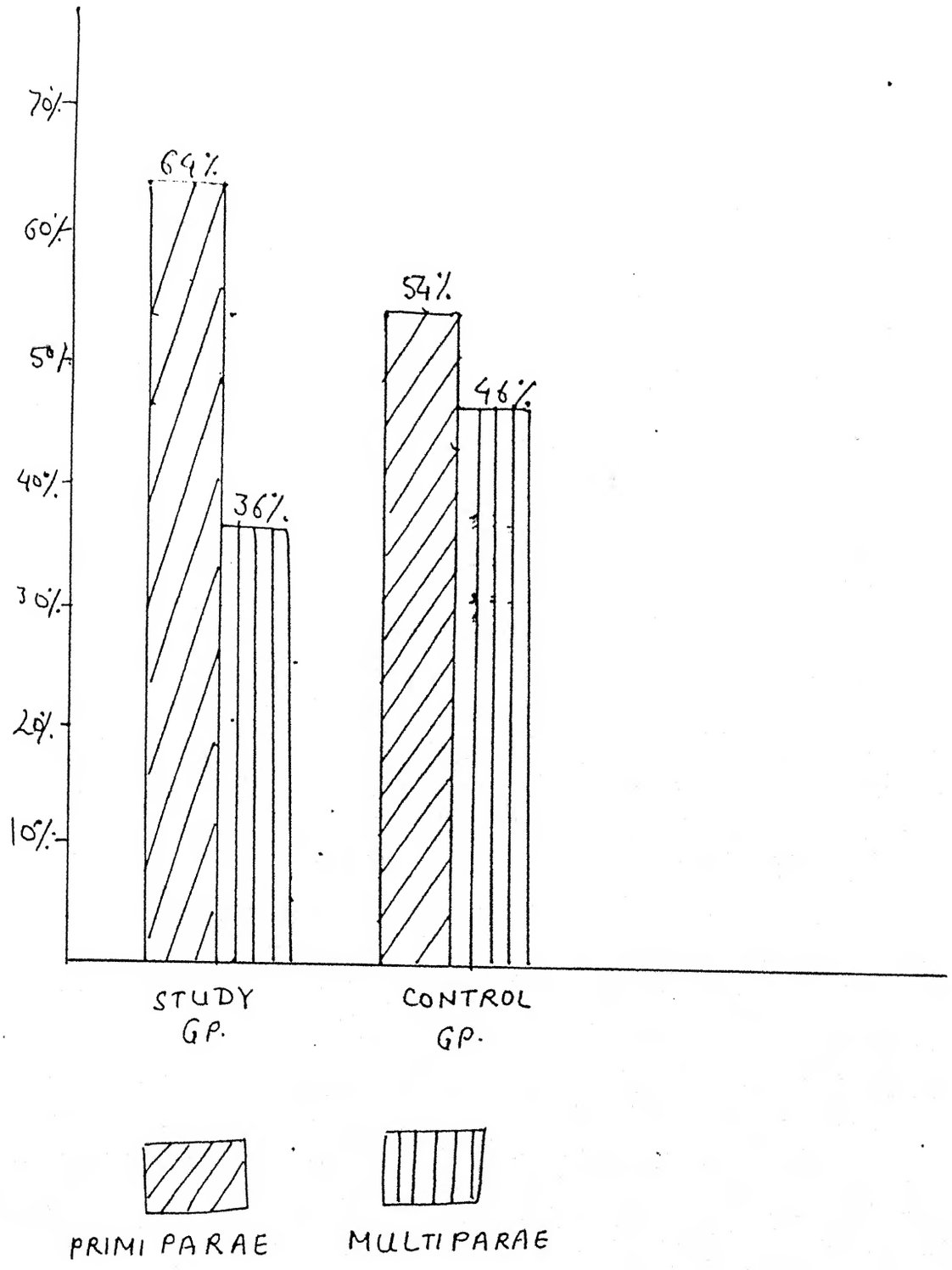
The age distribution in the study group and control group was similar statistically with mean value of 23.64 ± 3.47 and 23.70 ± 4.292 years respectively.

TABLE II : Distribution of cases according to their parity.

Parity	Group A	Group B
Primipara	64	54
Multipara	36	46
TOTAL	100	100


80%
70%
60%
50%
40%
30%
20%
10%
0%
16%
8%
62%
64%
14%
26%
8%
2%
< 20
20 - 25
26 - 30
31 - 35
AGE GP. (IN YEARS).
% age
STUDY GROUP.
CONTROL GROUP.

GRAPH SHOWING PARITY DISTRIBUTION.



The pattern of cervical ripening and induction of labour was compared between primiparae and multiparae in study and control groups. The number of primiparae requiring induction were more than multiparae in both groups. The distribution of primiparae and multiparae in the study and control group were statistically similar.

TABLE III : Distribution of cases according to their period of gestation.

Period of gestation (weeks)	Group A			Group B		
	Primi	Multi	Total	Primi	Multi	Total
37-38	24	10	34	14	16	30
39-40	6	6	12	6	6	12
7 41	34	20	54	34	24	58
Total	64	36	100	54	46	100

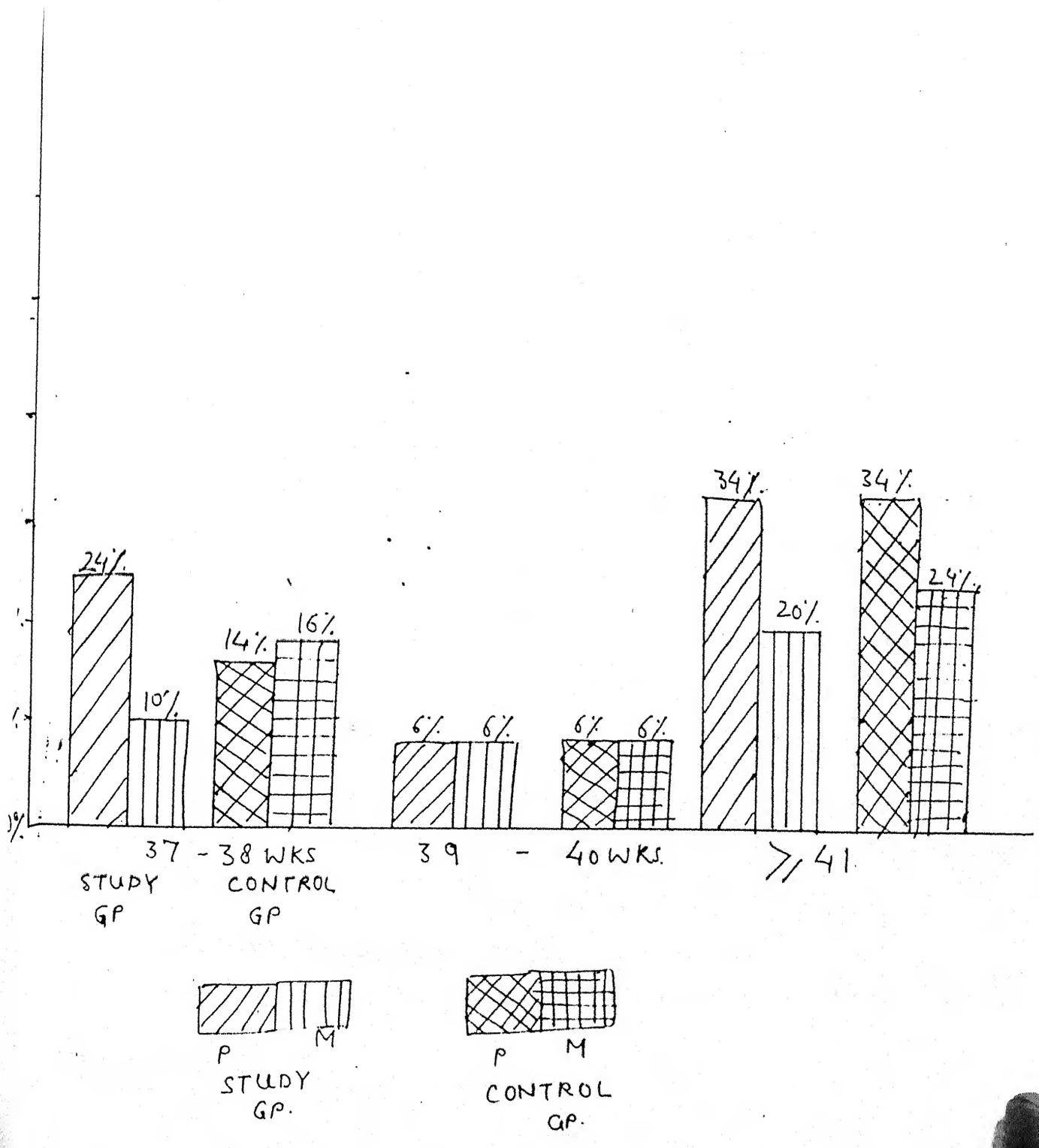
All the patients were at or near EDD or had crossed the due date.

TABLE IV : Distribution of cases according to indications for induction of labour.

Indications	Group A			Group B		
	Primi	Multi	Total	Primi	Multi	Total
Post maturity	34	19	53	34	23	57
PIH	26	9	35	20	17	37
Intrauterine death	2	6	8	-	4	4
Rh Negative	2	2	4	-	2	2
Total	64	36	100	54	46	100

Chief indications were postmaturity 53% in group A

GRAPH SHOWING PERIOD OF GESTATION IN WEEKS.



and 57% in group B and pregnancy induced hypertension was 35% in group A and 37% in group B.

TABLE V : Showing pre-induction cervical scoring.

Bishop score	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
1	2	3.10	-	-	-	-	-	-
2	26	40.63	12	33.33	10	18.52	4	8.69
3	32	50.00	12	33.33	6	11.12	8	17.39
4	4	6.27	10	27.78	24	44.44	26	56.53
5+	-	-	2	5.56	14	25.92	8	17.39
Total	64	100.0	36	100.0	54	100.0	46	100.0

TABLE VI : Showing preinduction cervical scoring.

Bishop score	Group A	Group B
1	2	-
2	38	14
3	44	14
4	14	50
5	2	22
TOTAL	100	100

All had unfavourable cervices and maximum (82%) had very low Bishop scores of 2 or 3 in group A. In group B maximum 72% cases had Bishop score of 4 or 5.

TABLE VII : Showing cervical scoring after 6 hours of induction.

Bishop score	GROUP A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
0 - 5	20	31.25	8	22.22	28	51.85	20	43.48
6 - 10	36	56.25	14	38.89	22	40.75	20	43.48
7 10	4	6.25	10	27.78	2	3.70	4	8.69
Delivered vaginally/ LSCS	4	6.25	4	11.11	2	3.70	2	4.35
TOTAL	64	100.0	36	100.0	54	100.0	46	100.0

TABLE VIII : Cervical scoring after 6 hours of induction.

Bishop Score	Group A	Group B
0 - 5	28	48
6 - 10	50	42
7 10	14	6
Delivered vaginally	8	4
TOTAL	100	100

28 percent cases of group A and 48 percent cases of group B did not have favourable cervical changes at the end of 6 hours of induction.

TABLE IX : Cervical scoring after 12 hours of induction.

Bishop Score	Group A					Group B				
	Primi		Multi		Total	Primi		Multi		Total
	No.	%	No.	%	%	No.	%	No.	%	%
0 - 5	10	15.62	4	11.11	14	12	22.22	8	17.39	20
6 - 10	12	18.75	6	16.67	18	18	33.34	14	30.44	32
7 10	24	37.50	10	27.78	34	12	22.22	10	21.74	22
Delivered vaginally	18	28.13	16	44.44	34	10	18.52	10	21.74	20
LSCS	-	-	-	-	-	2	3.70	4	8.89	6
Total	64	100.0	36	100.0	100	54	100.0	46	100.0	100

At the end of 12 hours after induction, 14 percent cases had unfavourable cervices in group A and 20 percent cases of group B. Six percent cases of group B could not be assessed due to caesarean section.

TABLE X : Cervical scoring after 24 hours after induction.

Bishop score	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
0 - 5	8	12.50	2	5.55	4	7.40	2	4.35
6 - 10	2	3.12	2	5.55	6	11.11	4	8.70
7 10	8	12.50	8	22.23	6	11.11	6	13.04
Delivered vaginally	40	62.50	24	66.67	26	48.15	24	52.17
LSCS	6	9.38	-	-	12	22.23	10	21.74
Total	64	100.00	36	100.00	54	100.00	46	100.00

TABLE XI : Cervical scoring after 24 hours of induction.

Bishop score	Group A	Group B
0 - 5	10	6
6 - 10	4	10
7 10	16	12
Delivered vaginally	64	50
LSCS	6	22
Total	100	100

At the end of 24 hours of induction, 10 percent patients continued to have unfavourable cervices and were regarded as failure cases for cerviprime intra-cervical gel. Six percent cases of group A could not be assessed due to caesarean section.

In group B, 6 percent cases continued to have unfavourable cervices and 22% cases could not be assessed due to caesarean section.

TABLE XII : Pattern of ripening of cervix at 6 hours of induction.

Bishop score	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
0 - 5	20	31.25	8	22.22	28	51.85	20	43.48
6 - 18	40	62.50	24	66.67	24	44.44	24	52.18
Delivered vaginally	4	6.25	4	11.11	2	3.71	2	4.34
Unassessed	-	-	-	-	-	-	-	-
Total	64	100.00	36	100.00	54	100.00	46	100.00

TABLE XIII : Pattern of ripening at 6 hours after induction.

Bishop score	Group A	Group B
0 - 5	28	48
6 - 13	64	48
Delivered vaginally	8	4
Unassessed	-	-
Total	100	100

TABLE XIV : Pattern of ripening after 12 hours of induction.

Bishop score	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
0 - 5	10	15.62	4	11.12	12	22.22	8	17.39
6 - 13	36	56.25	16	44.44	30	55.55	24	52.17
Delivered vaginally	18	28.13	16	44.44	10	18.53	10	21.74
Unassessed	-	-	-	-	2-	3.70	4-	8.70
Total	64	100.00	36	100.00	54	100.00	46	100.00

TABLE XV : Pattern of ripening after 12 hours of induction.

Bishop score	Group A	Group B
0 - 5	14	20
6 - 13	52	54
Delivered vaginally	34	20
Unassessed	-	6
Total	100	100

Success rate was 86% in group A and 74% in group B at 12 hours.

TABLE XVI : Pattern of ripening after 24 hours of induction.

Bishop score	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
0 - 5	8	12.50	2	5.56	4	7.47	2	4.35
6 — 13	10	15.62	10	27.78	12	22.22	10	21.74
Delivered vaginally	40	62.50	24	66.66	26	48.09	24	52.17
Unassessed	6	9.38	-	-	12	22.22	10	21.74
Total	64	100.00	36	100.00	54	100.00	46	100.00

TABLE XVII : Pattern of ripening after 24 hours of induction.

Bishop score	Group A	Group B
0 - 5	10	6
6 - 13	20	22
Delivered vaginally	64	50
Unassessed	6	22
Total	100	100

At the end of 24 hours, 10% cases continued to have unripe cervices and 6% cases could not be assessed due to caesarean section in group A while in group B, 6% cases continued to have unripe cervices and 22% cases could not be assessed due to LSCS.

TABLE XVIII : Pattern of induction-ripening interval.

Induction ripening interval (hrs)	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
< 6	44	78.57	28	82.36	26	54.17	26	68.44
6 - 12	10	17.86	4	11.76	20	41.67	8	21.53
12 - 24	2	3.57	2	5.88	2	4.16	4	10.63
Total	56	100.00	34	100.00	48	100.00	38	100.00
Mean±S.D.	7.61±2.71		6.8±2.11		9.71±4.44		9.15±5.78	

TABLE XIX : Pattern of induction ripening interval.

Induction ripening interval (hrs)	Group A		Group B	
	No.	%	No.	%
< 6	72	80.00	52	60.47
6 - 12	14	15.56	28	32.66
12 - 24	4	4.44	6	6.97
Total	90	100.00	86	100.00
Mean ± S.D.	7.32±2.52		9.45±5.05	

Maximum 72% cases of group A had ripening by 6 hours after cerviprime gel instillation and 52% cases of group B had ripening interval of 6 hours after oxytocin induction.

TABLE XX : Induction vaginal delivery interval.

Vaginal delivery interval (hours)	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
≤ 6	4	8.33	4	13.33	2	5.88	2	6.25
6 - 12	14	29.17	12	40.00	8	23.53	8	25.00
12 - 24	22	45.83	8	26.67	16	47.06	16	50.00
24 - 48	8	16.67	6	20.00	8	23.53	6	18.75
Total	48	100.00	30	100.00	34	100.00	32	100.00
Mean ±S.D.	16.21±5.75		15.55±8.11		19.92±8.02		17.13±7.21	

TABLE XXI : Induction vaginal delivery interval.

Interval (Hours)	Group A		Group B	
	No.	%	No.	%
≤ 6	8	10.26	4	6.06
6 - 12	26	33.33	16	24.24
12 - 24	30	38.46	32	48.48
24 - 48	14	17.95	14	21.22
Total	78	100.00	66	100.00
Mean±S.D.	15.97±6.68		18.64±7.71	

Maximum vaginal deliveries occurred in the period between 12-24 hours after induction in both the groups comprising a total of 38.46% in group A and 48.48% in group B.

TABLE XXII : Mode of delivery.

Mode of delivery	Group A					Group B				
	Primi		Multi		Total	Primi		Multi		Total
	No.	%	No.	%	%	No.	%	No.	%	%
Vaginal	48	75.00	30	83.33	78	34	62.96	32	69.57	66
Caesarean section	16	25.00	6	16.67	22	20	37.04	14	30.43	34
Total	64	100.0	36	100.0	100	54	100.0	46	100.0	100

78 cases delivered vaginally in group A as compared to 66 cases in group B and 22 cases in group A were delivered by caesarean section as compared to 34 cases in group B.

1 Vaginal delivery in the both group A and group B was assisted by forceps application.

TABLE XXIII : Type of vaginal delivery in study group.

Type of delivery	Primi		Multi		Total	
	No.	%	No.	%	No.	%
Spontaneous	20	41.67	12	40.00	32	41.03
Augmented	28	58.33	18	60.00	46	58.97
Total	48	100.00	30	100.00	78	100.00

Total of 32 (41.03%) cases in group A delivered spontaneously and 46 (58.97%) cases required augmentation by oxytocin.

TABLE XXIV : Outcome of augmentation.

Mode of delivery	Primi		Multi		Total	
	No.	%	No.	%	No.	%
Vaginal	28	63.64	18	75.00	46	67.65
Caesarean section	16	36.36	6	25.00	22	32.35
Total	44	100.00	24	100.00	68	100.00

Of all 46(67.65%) cases requiring augmentation in group A delivered vaginally and 22(32.35%) cases were delivered by caesarean section.

TABLE XXV : Indication for caesarean section.

Indication	Group A				Group B			
	Primi		Multi		Primi		Multi	
	No.	%	No.	%	No.	%	No.	%
Failed induction	8	50.00	2	33.33	4	20.00	2	14.29
Foetal distress	6	37.50	-	-	12	60.00	8	57.14
NPOL	2	12.50	4	66.67	4	20.00	4	28.57
TOTAL	16	100.00	6	100.00	20	100.00	14	100.00

TABLE XXVI : Indication for caesarean section.

Indication	Group A		Group B	
	No.	%	No.	%
Failed induction	10	45.45	6	17.65
Foetal distress	6	27.27	20	58.82
NPOL	6	27.28	8	23.53
TOTAL	22	100.00	34	100.00

Maximum 10(45.45%) cases had indication for caesarean section as failed induction in group A and 20 (58.82%) cases had indication as foetal distress in group B.

TABLE XXVII : Relation of pre-induction Bishop score to mode of delivery.

Groups	Mode of delivery	BISHOP SCORE 1		2		3		4		5	
		Primi	Multi	Primi	Multi	Primi	Multi	Primi	Multi	Primi	Multi
Study group (A)	Vaginal	-	-	18 (69.23)	8 (66.67)	26 (81.25)	10 (83.33)	4 (100.0)	10 (100.0)	-	2 (100.0)
	Caesarean section	1 (100.0)	-	8 (30.77)	4 (33.33)	6 (18.75)	2 (16.67)	-	-	-	-
	Total	2 (100.0)	-	26 (100.0)	12 (100.0)	32 (100.0)	12 (100.0)	4 (100.0)	10 (100.0)	-	2 (100.0)
Control group (B)	Vaginal	-	-	2 (20.00)	-	4 (66.67)	4 (50.00)	16 (66.67)	20 (76.92)	12 (85.71)	8 (100.0)
	Caesarean section	-	+	8 (80.00)	4 (100.0)	2 (33.33)	4 (50.00)	8 (33.33)	6 (23.08)	2 (14.29)	-
	Total	-	-	10 (100.0)	4 (100.0)	6 (100.0)	8 (100.0)	24 (100.0)	26 (100.0)	14 (100.0)	8 (100.0)

Figures in brackets are percentage.

TABLE XXVIII : Relation of pre-induction Bishop Score to mode of delivery.

Groups	Mode of delivery	BISHOP SCORE 1 No.	%	2 No.	%	3 No.	%	4 No.	%	5 No.	%
Study group (A)	Vaginal	-	-	26	68.42	36	81.82	14	100.00	2	100.00
	LSCS	2	100.00	12	31.58	8	18.18	-	-	-	-
	Total	2	100.00	38	100.00	44	100.00	14	100.00	2	100.00
Control group (B)	Vaginal	-	-	2	14.29	8	57.10	36	72.00	20	90.90
	LSCS	-	-	12	85.71	6	42.90	14	28.00	2	9.10
	Total	-	-	14	100.00	14	100.00	50	100.00	22	100.00

With low cervical scores cerviprime had higher rates of vaginal deliveries.

TABLE XXIX : Maternal complications.

Complications	Group A		Group B	
	No.	%	No.	%
PPH	2	25.00	6	28.07
Hypertonic uterine activity	2	25.00	6	28.07
Hyperpyrexia	4	50.00	10	42.86
GIT upset	-	-	-	-
TOTAL	8	100.00	22	100.00

Eight cases had complications in group A while 22 cases had complications in group B.

TABLE XXX : Foetal complications.

Complications	Group A		Group B 6	
	No.	%	No.	%
Asphyxia Neonatorum	8	8.70	14	14.58
Hyperbilirubinaemia	2	2.17	6	6.25
No complications	82	89.13	76	79.17
TOTAL	92	100.00	96	100.00

Ten (10.87%) cases in group A and 20(20.83%) babies in group B had complications in form of asphyxia neonatorum and hyperbilirubinaemia.

Eight cases in group A and 4 cases in group B had induction for intrauterine death. In addition, 10 babies in group A had 1 to 4 loops of cord round the neck and 12 babies in group B had 1 to 4 loops of cord round the neck.

TABLE XXXI : Apgar score at 5 minutes.

Apgar Score	Group A		Group B	
	No.	%	No.	%
∠ 7	4	4.35	14	14.58
7 - 8	34	36.96	52	54.17
9 - 10	54	58.69	30	31.25
TOTAL	92	100.00	96	100.00

Maximum 54 (58.69%) babies in group A had APGAR score of 9-10 and 52 babies (54.17%) in group B had APGAR score of 7-8.

TABLE XXXII : Outcome of treatment.

Factors	Group A	Group B	
Total No. of patients treated	100	100	
Mean pre-induction Bishop score	3.86±1.107	2.76±3.96	p ∠0.05
Total Vaginal deliveries	78	66	NSD
Successful ripening of cervices.	84	72	NSD
Ripening not assessed due to caesarean section before 24 hrs.	6	22	
Mean induction ripening interval	7.32±2.52	9.45±5.05	p ∠0.05
Mean induction delivery interval	15.97±6.68	18.64±7.71	p ∠0.05
Caesarean section	22	34	NSD
Maternal complications	8	22	p ∠0.05
Foetal complications	10	20	p ∠0.05

D I S C U S S I O N

DISCUSSION

The study was carried out at M.L.B. Medical College, Hospital, Jhansi in the year 1993-94. Total 100 women at or near term having unfavourable Bishop scores (0-5) were selected. Cerviprime (PGE_2) gel was instilled intracervically and oxytocin induction was started after 12 hours in those cases in whom the uterine contractions were not good.

100 more cases comparable with the study group for age, parity, indication for induction and cervical score were selected and were induced with intravenous oxytocin infusion.

The study group and control group were compared for the initial mean Bishop score. Bishop score at 6, 12, and 24 hours after induction of labour. Mode of delivery, foetal and maternal complications and APGAR score at 5 minutes were recorded.

AGE DISTRIBUTION

In present study maximum 62% cases of study group and 64% of control group were from 21-25 years of age. Next common age groups was 26-30 years, which comprised 14% of study group and 26% cases of control group. There were no patients above 35 years of age. The age distribution in both the groups A and B was statistically similar with mean values of 23.64 ± 3.474 and 23.70 ± 4.292 years respectively.

PARITY DISTRIBUTION

In present study, in the study group 64% cases were primiparae and 36% were multiparae wherease in control group there were 54% and 46% primiparae and multiparae respectively.

The pattern of cervical ripening and duration of labour was compared between primiparae and multiparae in study and control group. The number of primiparae requiring induction were more than multiparae in both the groups. The distribution of primiparae and multiparae in study and control group were statistically similar.

PERIOD OF GESTATION

All cases were at or near term or had crossed the expected due date. Maximum 54% cases of study group and 58% cases of control group were having 41 weeks or above. Next to this 34% cases in study group and 30% cases in control group were between 37-38 weeks of gestation.

INDICATIONS FOR INDUCTION

Chief indications were post maturity and post dated pregnancy which were 53% in study group and 57% in control group and still had no favourable change in the cervical state. Next in the order was pregnancy induced hypertension, 35% and 37% cases in study and control group respectively.

A group of 8 patients in the study group and 4 patients in the control group were induced for intra-

uterine death. Rh negative pregnancy was the indication for induction in 4 patients of study and 2 patients of control group.

Similar indications were found in the following:

Study	Indications	Percentage
Bernstein et al, 1987.	Post dated	61.54
	PIH	17.31
	Others	21.15

PRE-INSTILLATION CERVICAL SCORING

All cases had unfavourable cervical scoring ranging between 0-5. Maximum 84% cases had cervical score 0-3 in study group and 72% cases had cervical score 4-5 in the control group. Number of patients with low Bishop score were higher in the study group.

Similar scoring was seen in the following studies:

Study	Year	Cervical score	Percentage
Floberg et al,	1983	≤ 5	100.00
Ekbald et al,	1987	≤ 5	100.00
Rayburn et al,	1988	≤ 3	100.00
Baveja et al,	1988	≤ 3	100.00
Present study	1994	≤ 5	100.00

	Mean Bishop Score		p value
	Primiparous	Multiparous	
Study group	2.59±0.66	2.95±0.93	N.S.
Control group	3.77±1.05	3.95±1.18	N.S.
Mean Bishop score :	Study group -	2.76±2.96	<0.05
	Control group-	3.86±1.17	

In the study and control group tne Bishop score at 0 hours was not statistically different in the primiparaous and multiparous patients being 2.59 ± 0.66 & 2.95 ± 0.93 and 3.77 ± 1.05 & 3.95 ± 1.18 in the study and control group respectively.

Mean Bishop score was significantly more than in the control group as compared to the study group (3.86 ± 1.107 and 2.76 ± 2.96 respectively).

Mean initial cervical score in patients induced with oxytocin were significantly more favourable than those in PGE_2 patients in a study conducted by Turner et al(1987). This finding may be explained by a biss towards using gel in patients with unfavourable cervical state.

CERVICAL SCORING AT 6 HOUR AFTER INDUCTION

At the end of 6 hours as compared to 6.25% primiparous, 11.11% multiparous delivered in the study group and 3.7% primiparae and 4.35% multiparae delivered in the control group.

On comparing study and control groups 8% cases delivered in study and 4% in control group. 28% in group A and 48% in group B did not have favourable cervical changes at the end of 6 hours. 14% cases of study group and 6% of controls had bishop score more than 10.

CERVICAL SCORING AT 12 HOURS AFTER INDUCTION

At the end of 12 hours 28.12% primiparae and 44.44% multiparae had delivered veginally in the study

groups as compared to 18.52% of primiparae and 21.74% of multiparae in the control group. Total of 34% cases of study group delivered vaginally where only 20% cases delivered vaginally in control group. At the end of 12 hours, 6% cases in control group had undergone caesarean section.

15.62% primiparae and 11.11% multiparae continued to have unfavourable Bishop score in study group as compared to 22.22% primiparae and 17.39% of multiparae in control group. Thus constituting total of 14% in study group and 20% in control group. Bishop score could not be assessed in 6% cases of control group due to caesarean section.

The following studies showed the cervical status at 12 hours for the study group.

Study	Year	Favourable cervical status	Percentage of delivery
Ekbald et al,	1987	29.00	47.00
Rayburn et al	1988	35.59	37.29
Baveja et al, 1992	1992	32.10	37.60
Present study		52.00	34.00

In our study number of delivered patients were less as compared to the above studies, but number of patients having favourable cervical changes were more.

CERVICAL SCORING AT 24 HOURS AFTER INDUCTION

At the end of 24 hours, 62.5% primiparae and 66.67% multiparae delivered in study group as compared to 48.15% primiparae and 52.17% multiparae in the control

group. Thus constituting total of 64% in study group and 50% in control group.

In the study group 10% cases continued to have unfavourable cervices as compared to 6% cases in control group and were regarded as failure cases. 6% cases and 22% cases in study and control group respectively could not be assessed due to caesarean section. Follwwing studies also showed the cervical status after 24 hours of gel instillation.

Study	Year	Percentage of favourable cervices
Floberg et al	1983	82.00
William Wilkerson et al,	1985	87.50
Present study		90.00

PATTERN OF CERVICAL RIPENING

The effect of cerviprime and oxytocin on cervical ripening was evaluated by its effect on Bishop score at 6, 12, 24 hours in the study group.

TABLE : Cervical scoring in study group.

Time (Hrs)	Mean Bishop score		p value
	Primiparae	Multiparae	
0	2.59±0.66	2.95±0.93	N.S.
6	7.93±2.10	8.31±2.30	N.S.
12	10.47±2.5	10.60±1.64	N.S.
24	10.55±2.18	11.16±3.12	N.S.

The Bishop score at 0, 6, 12 and 24 hours was not statistically different in the primiparous and multiparous patients being 2.59±0.66 Vs 2.95±0.93, 7.63±2.1 Vs 8.31±2.3,

10.47±2.5 Vs 10.60±1.64, and 10.55±2.18 Vs 11.16±3.12 respectively. This shows similar trend in rise of Bishop score in both primiparous and multiparous patients.

TABLE : Cervical scoring in control group.

Time (Hrs)	Mean Bishop score		p value
	Primiparae	Multiparae	
0	3.77±1.05	3.95±1.18	N.S.
6	5.84_+2.03	6.72±2.54	N.S.
12	8.42±3.05	8.70±3.01	N.S.
24	9.12±3.31	10.33±3.44	N.S.

The Bishop score of 0 hour was not statistically different in the study Vs control group (3.77±1.05 Vs 3.95±1.18). Also the Bishop score at 6, 12 and 24 hours was not statistically different i.e. 5.84±2.03 Vs 6.72± 2.54, 8.42±3.05 Vs 8.7±3.01 and 9.12±3.31 Vs 10.33±3.44 respectively. Thus the rise of Bishop score after oxytocin induction was similar in both primiparous and multiparous patients.

TABLE : Comparison of cervical scoring in study and control groups.

Time (hrs)	Mean Bishop score		p value
	Study group	Control group	
0	2.76±2.96	3.86±1.107	<0.05
6	6.348±3.226	6.25±2.302	<0.05
12	8.939±3.44	8.53±3.002	N.S.
24	9.633±3.662	9.603±3.296	N.S.

The effect of cerviprime and oxytocin on Bishop score was compared.

The Bishop score at 0 hours was significantly more in control group as compared to study group (3.86± 1.107 Vs 2.76±2.96). This finding may be emphasized by a bias towards using gel in patients with unfavourable cervical score. Similar difference in mean Bishop score was observed by Turner et al (1987). The rise in Bishop score was significantly more in cerviprime group, than in oxytocin group at 6 hours(6.348±3.226 Vs 6.25±2.302).

Thus showing PGE_2 gel significantly improves the mean cervical scores. This being previously demonstrated by Calder et al (1977), Buchanen et al (1984) and Trofatter et al (1985).

The mean Bishop score at 12 hours and 24 hours in the study and control group was significantly not different being 8.939±3.44 Vs 8.53±3.002 and 9.633±3.662 Vs 9.603±3.296 respectively, though the mean Bishop score was more with cerviprime group than oxytocin group. Thus showing trend towards more improvement.

In study group 10% and 6% cases in control group continued to have unfavourable Bishop scores at the end of 24 hours and were labelled as failure cases. In study group patients, patients with unfavourable cervix had induction with oxytocin for further 8 hours.

The results of various studies for study groups are given in table showing changes over a period of 12-24 hours.

Study	Bishop score Before/After	No.of cases
Floberg et al, 1983	3.2/7.7	42
Theiry et al, 1984	3.4/6.6	40
Guz et al, 1985	3.0/9.0	50
Trofatter et al, 1985	1.2/6.7	30
Bernstein et al, 1987	2.9/5.1	55
I.C.M.R. study, 1988	$\angle$3.0/ 76.0	221
Present study	2.76/9.633	100

INSTILLATION RIPENING INTERVAL

Maximum 72% and 52% patients had ripening of cervix at 6 hours in study and control group respectively. The mean induction ripening interval in primiparous and multiparous patients was 7.61$\pm$2.71 Vs 6.8$\pm$2.11 hours respectively in the study group as compared to 9.71$\pm$4.44 Vs 9.15$\pm$5.78 hours in the control group. The difference was not statistically significant between primiparous and multiparous patients in both study and control. Thus showing similar effect of PGE_2 gel and oxytocin in primiparous and multiparous patients.

The mean induction ripening interval was higher in control group (9.45$\pm$5.05 hours) as compared to study group (7.32$\pm$2.52 hours) and the difference was statistically significant ($p \angle 0.05$). This shows the improved effect of cerviprime on ripening of cervix. Turner et al (1987) and Ferguson et al (1988) showed a similar effect of cerviprime on ripening of cervix.

INDUCTION VAGINAL DELIVERY INTERVAL

Maximum vaginal deliveries (30%) of both the groups occurred between 12-24 hours. The induction vaginal delivery interval in both study and control group in primiparous patients as compared to multiparous was statistically not different being 16.21±5.85 Vs 15.55±8.11 hours in study group and 19.92±8.02 Vs 17.13±7.21 hours in control group. Though a trend towards reduced induction delivery interval was seen in multiparous patients in both the groups which could be related to improved pre-induction mean Bishop scores in multiparous patients in both the groups.

Mean induction delivery interval in the study group as compared to control group was significantly lower (15.97±6.18 Vs 18.64±7.71 hours; $p < 0.05$). It shows effect of improved/cerviprime on induction delivery time. Turner et al (1987) showed trend towards shorter labours in patients with cerviprime followed by oxytocin when compared to oxytocin alone group.

Artur Silver Cruz et al (1985) showed the mean induction delivery interval of 11.83 hours for multiparous patients and 7.83 hours for multiparous patients induced with cerviprime gel. The values are lower than that observed in present study.

MODE OF DELIVERY

In study group 78% cases delivered vaginally while 66% cases delivered vaginally in control group. One case in

each group was assisted by forceps. The two induction method did not differ significantly in the rates of vaginal deliveries and caesarean section. Though trend towards increased rate of caesarean section was seen in the control group. Wiquist et al (1986), Kristofferson et al (1986) showed no significant difference in the caesarean section rate.

In the study group, 25% primiparous and 16.66% multiparous were delivered by caesarean section as compared to 37.04% of primiparous and 30.43% of multiparous in control group. The difference in primiparous and multiparous in both the groups was hot statistically significant though a increased trend of caesarean section was seen in primiparous patients sf which could be correlated to improved though not statistically significant mean pre-induction cervical score in multiparous patients.

The rate of caesarean section was lower in study group (22%) as compared to control group (34%) and the difference was not statistically significant. It can be inferred that despite significantly low mean pre-induction Bishop score in the study group as compared to control group, a decreasing trend of caesarean section was seen in the study group. Thus showing improved effect of PGE_2 gel over vaginal deliveries in patients with low pre-induction Bishop score.

RESULTS OF PREVIOUS STUDIES FOR STUDY GROUP.

Study	Percentage of delivery	
	Vaginal	L.S.C.S.
Floberg et al, 1983	90.00	10.00
Grunberger et al, 1984	83.00	17.00
Artur Silva et al, 1985	96.00	4.00
Ekbald et al, 1987,	67.00	33.00
Bernstein et al, 1987	69.30	30.70
Rayburn et al, 1988	76.00	24.00
Baveja et al, 1988	81.70	18.30
Present study	78.00	22.00

Results of Rayburn et al (1988) are comparable to the results of present study.

TYPES OF VAGINAL DELIVERY

Of the total vaginal deliveries, 41.67% cases delivered spontaneously whereas 58.33% required augmentation by oxytocin in the study group. Results of other studies are as follows :

Study	Type of vaginal delivery	
	Spontaneous	Augmentation
Kenneth et al, 1985	63.00	37.00
Bernstein et al, 1987	53.00	47.00
Present study	41.67	58.33

OUTCOME OF AUGMENTATION

Of the total augmented cases, 67.65% delivered vaginally while 32.35% cases required caesarean section. The success rate of vaginal delivery following augmentation was higher in multiparous(75%) than in primiparous(63.64%).

RELATION OF PRE-INDUCTION BISHOP SCORE WITH MODE OF DELIVERY

At low Bishop score of 2 and 3, cerviprime had significantly higher vaginal deliveries (68.42% and 81.82%) as compared to oxytocin (14.29% and 57.1%) while at cervical score of 4 and 5, the ratio of vaginal deliveries with cerviprime as 100% and with oxytocin it was 72% and 90.9% respectively and difference was not statistically significant.

This infers that intracervical cerviprime is better agent for induction and priming in patients with very low cervical scores.

INDICATION FOR CAESAREAN SECTION

In the cerviprime group, maximum 10(45.45%) cases of caesarean section were done for failed induction 6(27.28%) for foetal distress.

In the oxytocin group, however, maximum 20(50%) cases of caesarean section were done for foetal distress which is a common complication of oxytocin infusion. 6(17.65%) were done for failed induction and 8(23.53%) were done for nonprogress of labour.

All the patients of caesarean section in cerviprime group were augmented by oxytocin. Indication for caesarean section in other studies for study group are given ihelow.

Indication	Percentage
Bernstein et al, 1987	
Failure to progress	68.75
Foetal distress	25.00
Unripe cervix	6.25
Baveja et al, 1988	
Foetal distress	75.00
Hypertonic uterine contraction	12.50
PROM	12.50
Present study,	
Failed induction	45.45
Foetal distress	27.27
NPOL	27.28

OUTCOME OF TREATMENT

In the present study, overall outcome of treatment showed a success rate of 78% in the study group and 66% in the control group.

In the study group 8(12.5%) primiparous and 2(5.56%) multiparous patients, thus total of 10% cases and in control group 4(7.4%) primiparous and 2(4.35%) multiparous patients, thus total of 6% cases had unripe cervices at 24 hours. Six patients in study group and 22 patients in control group could not be assessed at 24 hours due to caesarean section. Ten patients of study group having unripe cervices were further augmented with oxytocin for 8 hours. No effect on ripening of cervix was seen and all patients underwent caesarean section. Studies showing the success rates for ripening of cervix in study group at 24 hours are given below:

Study	Percentage of		
	Success	Failure	Unassessed
Grunberger et al, 1984	84.50	3.90	11.60
William Wilkerson et al, 1985.	87.50	12.50	-
Baveja et al, 1988	69.70	25.80	4.50
Present study	90.00	10.00	-

MATERNAL COMPLICATIONS

In present study, 2(25%) cases of study group had hypertonic uterine activity, 4(50%) cases had hyperpyrexia and 2(25%) cases had post partum haemorrhage, thus in study group, out of 100 patients only 8(8%) cases had complications. All cases developing complications were augmented with oxytocin. In group B, 22 cases developed complications in the form of hyperpyrexia in 10(42.86%) cases, hypertonic uterine activity in 6(35.71%) cases. Thus intracervical PGE_2 gel had significantly lower rate of complication as compared to intravenous oxytocin. This could be attributed the fact that cerviprime was instillated locally and it has less systemic side effects. Other studies showing maternal complication rate for intracervical PGE_2 gel group are given below.

Complication	Percentage
Bernstein et al, 1987	
Hyperactivity of uterus	3.85
Raytwin et al, 1988	-
Baveja et al, 1988	-
Present study	-

FOETAL COMPLICATIONS

In the study group, 8(8.7%) babies had asphyxia neonatorum and 2(2.17%) babies had neonatal jaundice. While in control group 14(14.58%) babies had asphyxia neonatorum and 6(6.25%) had neonatal jaundice. 8 cases had induction for intrauterine death in study group as compared to 4 cases in control group. Thus feetal complications with cerviprime gel was 10.87% as compared to oxytocin (20.83%).

This could be attributed to minimal systemic absorption of intracervical PGE_2 gel as compared to oxytocin.

Foetal complications found in other studies with PGE_2 gel are given below :

Study	Complication percentage
Floberg et al, 1983	-
Ekbald et al, 1987	21.00
Baveja et al, 1988	3.17
Present study	10.87

APGAR SCORE AT 5 MINUTES

Four (4.35%) babies in study group had APGAR score less than 7 as compared to 14 babies (14.58%) in control group which was significantly lower. There was only 1 neonatal death in study group and 2 in control group. Cause of death could not be identified.

Ten foetuses in study and 12 in control groups were seen to have 1-4 loops of umbilical cord round the neck at the time of delivery. All had good APGAR score.

EFFICACY OF INTRACERVICAL PGE_2 FOR INDUCTION IN CASES OF IUD

Intracervical PGE_2 has been found to have very good effect on induction of labour in cases of IUD with mean induction delivery interval of 6.62 hours though the series comprised of only 8 cases. None of the case required augmentation with oxytocin and no side effect was seen.

The mean induction delivery interval in cases of IUD in control group (Oxytocin alone group) was 10 hours which was significantly higher than intracervical PGE_2 gel (6.62 hours).

OUTCOME OF TREATMENT

On overall assessment of the efficacy of intracervical PGE_2 gel as compared to of intravenous oxytocin, In the present study, there was no significant difference in the mode of delivery - vaginal and caesarean section. The induction delivery interval was significantly lower in the PGE_2 gel group.

Considering the delivery rates for low pre-induction Bishop score cases, vaginal deliveries were significantly higher in the PGE_2 gel group. Maternal and foetal complications were lower in the study group than intravenous oxytocin group.

The results of our study lead us to conclude that intracervical PGE_2 gel followed by intravenous infusion of oxytocin is safe and effective method of inducing labour in patients with an unripe cervix.

SUMMARY AND CONCLUSION

SUMMARY AND CONCLUSION

1. In present study, 100 pregnant women admitted in M.L.B. Medical College, Hospital, Jhansi were induced with PGE_2 gel(cerviprime) applied endocervically and were compared with 100 patients induced with intravenous oxytocin infusion.
2. 200 patients were selected as per the inclusion criteria, complete obstetric examination was done and routine investigations such as blood haemoglobin, urine routine and microscopic, blood grouping and typing was done. All had indication for induction of labour. Pelvic examination was done and intracervical PGE_2 gel (cerviprime) was instilled in 100 patients of the study group. 100 patients of the comparison group were induced with intravenous oxytocin.
3. Maximum 62% cases in study group and 64% in control group were in the age group from 20-25 years.
4. In both study and control groups, primipara were more than multiparae(64% & 36% and 54% & 46% respectively).
5. Maximum cases had gestational age of 41 weeks or above (54% in study and 58% in control group).
6. Chief indication for induction were postmaturity and post dated pregnancy, 53% and 35% respectively in the study group and 57% and 37% respectively in the control group.

7. All cases had unfavourable preinduction mean Bishop score in both the groups. Mean Bishop score in the study group in primiparous and multiparous patients was 2.59 ± 0.66 and 2.95 ± 0.93 and in control group it was 3.77 ± 1.05 and 3.95 ± 1.18 respectively which was not significantly different in both the groups. Mean Bishop score was significantly lower in the study group (2.76 ± 2.96) than in the control group(3.86 ± 1.1).

8. Cervical scoring was done at 6, 12 and 24 hours in both the groups. The study was considered to be successful. If Bishop score at 24 hours after administration of gel or after I.V. oxytocin was 6 or more or women had delivered vaginally before this cut off point. 84% cases in the study group and 72% cases in the control group had cervical scores 6 or more than 6, or had delivered vaginally. 10 cases in the study group and 6 cases in the control group were considered as failure as Bishop scores could not improve to 6 or 76 in 24 hours. Six cases in study and 22 cases in control group were unassessed as they underwent caesarean section before 24 hours. Of these all cases in study group and 11 cases in control group had favourable cervical scores of 6 or more than 6 before they underwent caesarean section.

9. Maximum 64% patients in group A and 48% in group B had ripening of cervix by 6 hours. Multipara required

lesser period than primiparae (6.8±2.11, 7.61±2.71 in study group and 9.15±5.78 and 9.71±4.44 hours in control group respectively) but the difference was not statistically significant. The mean induction ripening interval was significantly lower in the study group as compared to control group (7.32±2.52 and 9.45±5.05 hours respectively).

10. Maximum vaginal deliveries (30%) in study group and 32% in control group were occurred between 12-24 hours. Mean induction delivery interval was significantly lower in the study group as compared to control group (15.97±6.68 and 18.44±7.71 hours). Multiparae required apparently lesser period than primiparae in both the groups (15.55± 8.11, 16.21±5.85 hours in study group and 17.13±7.21, 19.92±8.02 hours in control group) which was statistically insignificant.

11. 78% cases in the study group delivered vaginally(spontaneous or augmented) as compared to 66% in cases of control group. Rest 22% cases in study group and 34% in control group were delivered by caesarean section. There was no significant difference in caesarean section between the two groups.

12. Chief indications for caesarean section were failed induction (45.45%) and non progress of labour (27.28%) in study group and foetal distress (58.82%) and failed induction (17.65%) in control group.

13. Study group had significantly lower maternal complication rate (8%) as compared to control group (22%).

14. 4.35% babies in the study group had APGAR score less than 7 at 5 minutes as compared to 14.58% in the control group which was significantly lower. Foetal complications rate in study group was 10.87% as compared to 20.83% in control group. There was 1 neonatal death in the study group and 2 in the control group. Thus foetal complications were less in the study group than in the control group.

Conclusion

From the present study the following conclusions were drawn :

1. Endocervical instillation of PGE_2 gel (cerviprime) was particularly well suited for the induction of labour in the patients with unripe cervix, because of its combined properties of cervical ripening and induction of labour.

2. In a single low dose (0.5 mg) endocervical (PGE_2) gel was safe and effective method for priming and induction.

3. There was definite success in ripening of the cervix.

4. Main advantage with cerviprime was that with low preinduction Bishop score (1,2,3) cerviprime (alone or augmented), had definitely increased number of vaginal deliveries(78%) as compared to intravenous oxytocin of 66%.

5. The mean induction delivery interval with cerviprime was significantly lower (15.97±6.68 hours) as compared to intravenous oxytocin (18.44±7.71 hours).

6. Maternal complications were less (8% with cerviprime gel) as compared to intravenous oxytocin (22%).

7. Neonatal complications were less (10.87%) with cerviprime as compared to intravenous oxytocin (20.83%).

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A P P E N D I X

APPENDIX - I

MASTER CHART

PGE_2 Gel group (Study group)

Sl. No.	Name	Age (yrs)	B.P.	Urine albumin	Parity	G.A. (weeks)
1.	2	3	4	5	6	7
1.	Shashi	20	110/64	-	Po	41
2.	Rekha	21	110/80	-	Po	41
3.	Mamta	25	110/70	-	Po	41
4.	Anita	25	114/80	-	Po	42
5.	Sagun	22	120/84	-	Po	41
6.	Babita	25	110/80	-	Po	41
7.	Maya	20	120/86	-	Po	41
8.	Sudha	21	120/84	-	Po	42
9.	Mamta	21	110/80	-	Po	42
10.	Shamin	22	112/84	-	Po	41
11.	Nirmala	19	110/88	-	Po	41
12.	Mithla	25	110/84	-	Po	42
13.	Rekha	22	110/80	-	Po	42
14.	Anita	18	120/84	-	Po	41
15.	Girja	20	120/88	-	Po	41
16.	Hemant Kumari	21	124/80	-	Po	44
17.	Pramila	25	120/82	-	Po	41
18.	Savita	25	110/86	-	Po	42
19.	Seema	22	110/70	-	Po	41
20.	Usha	25	110/78	-	Po	41
21.	Vandana	20	120/80	-	Po	41
22.	Janki	25	120/68	-	Po	42
23.	Seeta	21	120/72	-	Po	42
24.	Kranti	22	118/78	-	Po	41
25.	Narveda	19	110/80	-	Po	41
26.	Kamlesh	25	112/84	-	Po	42
27.	Manjoo	22	110/80	-	Po	42
28.	Seema	18	120/84	-	Po	41
29.	Geeta	24	160/94	-	Po	37
30.	Sandhya	24	170/110	1+	Po	38
31.	Mahrunisha	23	160/110	-	po	38
32.	Radha	21	170/100	-	Po	39

Sl. No.	Indication for induction	Bishop Score at PI	6H	12H	24H	Synto-augmen-tation	I.P.I. (hours)	I.D.I. (hours)
	8	9	10	11	12	13	14	15
1.	Post dated	2	4	5	13	IV Oxytocin	24	25
2.	"	3	10	13	-	-	6	14
3.	"	2	6	13	-	IV Oxytocin	6	16
4.	"	3	10	13	-	"	6	16
5.	"	3	5	11	13	"	12	25
6.	"	3	8	-	-	-	6	11
7.	"	2	10	-	-	-	6	11
8.	"	3	5	8	-	IV Oxytocin	12	20
9.	"	3	6	13	-	"	6	20
10.	"	2	5	7	11	"	12	26
11.	"	2	10	-	-	-	6	10
12.	"	3	9	13	-	-	6	15
13.	"	4	7	12	-	IV Oxytocin	8	17
14.	"	4	-	-	-	-	< 6	5
15.	"	2	4	5	13	IV Oxytocin	24	25
16.	"	3	10	13	-	"	6	14
17.	"	2	6	13	-	"	6	16
18.	"	3	10	13	-	"	6	16
19.	"	3	5	11	13	"	12	25
20.	"	3	8	-	-	-	6	-
21.	"	2	10	-	-	-	6	-
22.	"	3	3	8	10	IV Oxytocin	12	20
23.	"	3	6	13	-	"	6	20
24.	"	2	5	7	11	"	12	26
25.	"	2	10	-	-	-	6	10
26.	"	3	9	13	-	IV Oxytocin	6	15
27.	"	4	7	12	-	"	6	17
28.	"	4	-	-	-	-	< 6	5
29.	PET	3	9	-	-	-	6	9
30.	"	2	5	12	-	IV Oxytocin	6	18
31.	"	3	8	13	-	-	6	14
32.	"	2	10	13	-	IV Oxytocin	6	14

Sl. No.	Mode of delivery	Indication for LSCS	Maternal Compli-cations	APGAR at 5 minutes	Neonatal Compli-cations
	16	17	18	19	20
1.	Vag.	-	-	7/10	-
2.	Vag.	-	-	8/10	-
3.	Vag.	-	-	8/10	-
4.	Vag.	-	-	7/10	-
5.	Vag.	-	PPH	9/10	-
6.	Vag.	-	-	7/10	-
7.	Vag.	-	-	9/10	-
8.	Vag.	-	-	8/10	-
9.	Vag.	-	-	8/10	-
10.	Vag.	-	-	9/10	-
11.	Vag.	-	-	7/10	-
12.	Vag.	-	-	7/10	-
13.	Vag.	-	-	7/10	-
14.	Vag.	-	-	7/10	-
15.	Vag.	-	-	10/10	-
16.	Vag.	-	-	9/10	-
17.	Vag.	-	-	8/10	-
18.	Vag.	-	-	9/10	-
19.	Vag.	-	-	8/10	-
20.	Vag.	-	-	10/10	-
21.	Vag.	-	-	8/10	-
22.	Vag. (F)	-	-	7/10	-
23.	Vag.	-	-	9/10	-
24.	Vag.	-	Hyper pyrexia	7/10	-
25.	Vag.	-	-	9/10	-
26.	Vag.	-	-	8/10	-
27.	Vag.	-	-	8/10	-
28.	Vag.	-	-	9/10	-
29.	Vag.	-	-	7/10	-
30.	Vag.	-	-	8/10	-
31.	Vag.	-	-	9/10	-
32.	Vag.	-	-	9/10	-

1	2	3	4	5	6	7
33.	Dimple	25	170/110	2+	Po	38
34.	Manjoo	23	160/102	-	Po	38
35.	Aneeta	20	150/110	-	Po	38
36.	Rani	21	140/110	1+	Po	37
37.	Mewadevi	24	150/110	-	Po	39
38.	Poonam	24	150/100	-	Po	38
39.	Kamini	23	150/98	2+	Po	38
40.	Yashoda	21	150/100	-	Po	39
41.	Sunita	25	160/100	-	Po	38
42.	Anita	23	158/106	1+	Po	38
43.	Rafiya	20	150/98	-	Po	38
44.	Babli	21	160/100	-	Po	37
45.	Mantoo	18	110/80	-	Po	38
46.	Suman	18	120/84	-	Po	38
47.	Munni	18	110/80	-	Po	38
48.	Subhadra	18	110/84	-	Po	38
49.	Chhaya	22	110/88	-	Po	41
50.	Mamta	26	110/80	-	Po	41
51.	Hemlata	25	120/84	-	Po	42
52.	Suneeta	22	120/80	-	Po	41
53.	Shakun	28	110/84	-	Po	41
54.	Sangeeta	23	100/70	-	Po	41
55.	Nandana	27	170/80	-	Po	41
56.	Sangeeta	23	110/84	-	Po	42
57.	Rekha	22	120/80	1+	Po	41
58.	Kancham	20	120/80	-	Po	41
59.	Tabassum	25	110/70	-	Bo	37
60.	Kastoori	22	110/70	1+	Po	38
61.	Jaishree	28	120/74	-	Po	39
62.	Indrani	23	114/80	1+	Po	37
63.	Guddi	27	112/70	-	Po	38
64.	Sultana	23	110/70	-	Po	39
65.	Munni	22	110/84	-	P_1	42
66.	Ramkanti	25	110/86	-	P2	41

	8	9	10	11	12	13	14	15
33.	PET	3	9	13	-	IV Oxytocin	6	17
34.	"	2	5	-	6	"	6	12
35.	"	3	10	-	-	-	6	11
36.	"	3	8	13	-	IV Oxytocin	6	18
37.	"	3	9	-	-	-	6	9
38.	"	2	5	12	-	IV Oxytocin	6	18
39.	"	3	8	13	-	"	6	14
40.	"	2	10	13	-	"	6	14
41.	"	3	9	13	-	"	6	17
42.	"	2	5	-	-	-	6	12
43.	"	3	10	-	-	-	6	11
44.	"	3	8	13	-	IV Oxytocin	6	18
45.	Rh Negative	3	12	-	-	-	6	10
46.	"	3	11	-	-	-	6	11
47.	I.U.D.	2	-	-	-	-	-	5
48.	"	3	-	-	-	-	-	6
49.	Post dated	3	5	6	-	IV Oxytocin	12	22
50.	"	1	3	5	5	"	FR	36
51.	"	2	2	5	5	"	FR	34
52.	"	2	3	5	5	"	FR	34
53.	"	2	5	5	5	"	FR	34
54.	"	2	8	8	-	"	6	16
55.	"	3	6	11	13	"	6	25
56.	"	3	11	13	-	"	6	19
57.	"	3	5	6	-	"	12	18
58.	"	1	3	5	5	"	FR	32
59.	PET	2	3	5	5	"	FR	32
60.	"	2	2	5	5	"	FR	32
61.	"	2	4	5	5	"	FR	32
62.	"	2	8	8	-	"	6	20
63.	"	3	11	13	-	"	6	19
64.	"	3	6	11	13	"	6	25
65.	Post dated	2	8	13	-	"	6	16
66.	"	3	8	13	-	"	6	21

	16	17	18	19	20
33.	Vag.	-	-	8/10	-
34.	Vag.	-	-	9/10	-
35.	Vag.	-	-	9/10	-
36.	Vag.	-	-	9/10	-
37.	Vag.	-	-	10/10	-
38.	Vag.	-	-	10/10	-
39.	Vag.	-	-	9/10	-
40.	Vag.	-	-	8/10	-
41.	Vag.	-	-	9/10	-
42.	Vag.	-	-	8/10	-
43.	Vag.	-	-	9/10	-
44.	Vag.	-	-	9/10	-
45.	Vag.	-	-	9/10	-
46.	Vag.	-	-	9/10	-
47.	Vag.	-	-	Dead baby	-
48.	Vag.	-	-	" "	-
49.	CS	FD	-	9/10	-
50.	"	FI	Hyper pyrexia	5/10	A.N.
51.	"	FI	-	9/10	-
52.	"	FI	-	8/10	-
53.	"	FI	-	9/10	-
54.	"	FD	H.U.A.	6/10	A.N.
55.	"	NPOL	-	7/10	-
56.	"	FD	-	6/10	A.N.
57.	"	FD	Hyper pyrexia	6/10	A.N.
58.	"	FI	-	9/10	-
59.	"	FI	-	7/10	-
60.	"	FI	-	7/10	-
61.	"	FI	-	9/10	-
62.	"	FD	H.U.A.	7/10	-
63.	"	FD	-	9/10	-
64.	"	NPOL	-	9/10	-
65.	"	-	-	-	-
66.	"	-	-	7/10	-

1	2	3	4	5	6	7
67.	Nargis	35	114/86	-	P3	42
68.	Mamta	25	120/88	-	P1	41
69.	Sadhna	31	124/80	-	P2	41
70.	Pushpa	26	110/84	-	P1	41
71.	Ram Kumari	22	114/82	-	P1	42
72.	Geeta	25	116/84	-	P2	41
73.	Tara	22	110/84	-	P1	42
74.	Suman	25	110/86	-	P2	41
75.	Kiran	35	114/84	-	P3	42
76.	Gayatri	25	120/88	-	P1	41
77.	Mubeena	31	120/84	-	P2	41
78.	Usha	26	110/84	-	P1	41
79.	Laxmi	22	114/82	-	P1	42
80.	Shanti	25	116/84	-	P2	41
81.	Sangeeta	21	160/110	-	P1	40
82.	Rama	22	170/100	1+	P1	37
83.	Sangeeta	21	160/114	-	P1	40
84.	Pushpa	21	164/110	1+	P2	40
85.	Maya	22	170/114	-	P1	37
86.	Kiran	21	180/100	1+	P1	40
87.	Kalawati	28	112/84	-	P1	38
88.	Bitti	35	110/82	-	P2	37
89.	Kala	35	114/86	-	P2	37
90.	Mithlesh	28	112/84	-	P2	37
91.	Meera	35	110/86	-	P2	38
92.	Anwari	35	120/88	-	P1	37
93.	Premwati	26	124/84	-	P2	39
94.	Suman	27	120/84	-	P1	38
95.	Prabha	22	120/84	-	P2	41
96.	Yasmeen	28	110/84	-	P2	41
97.	Sunita	22	160/106	2+	P1	38
98.	Savitridevi	28	180/110	2+	P1	39
99.	Chameli	22	180/116	1+	P1	38
100.	Rati	22	170/120	1+	P1	38

	8	9	10	11	12	13	14	15
67.	Post dated	5	-	-	-	-	<6	5
68.	"	3	13	-	-	-	6	8
69.	"	2	5	10	13	IV Oxytocin	12	25
70.	"	3	8	-	-	"	6	12
71.	"	4	13	-	-	-	6	7
72.	"	3	5	10	13	IV Oxytocin	12	28
73.	"	4	8	12	-	"	6	20
74.	"	4	8	13	-	"	6	20
75.	"	4	13	-	-	"	6	12
76.	"	4	8	13	-	"	6	20
77.	"	2	8	13	-	"	6	16
78.	"	3	8	13	-	"	6	21
79.	"	5	-	-	-	-	<6	5
80.	PET	3	13	-	-	-	6	8
81.	"	2	5	10	13	IV Oxytocin	12	25
82.	"	3	8	-	-	"	6	12
83.	"	4	13	-	-	-	6	7
84.	"	3	5	10	13	IV Oxytocin	12	28
85.	"	4	8	12	-	"	6	20
86.	"	4	8	13	-	"	6	20
87.	I.U.D.	3	-	-	-	-	<6	5
88.	"	4	13	-	-	-	6	8
89.	"	2	11	-	-	-	6	9
90.	"	4	-	-	-	-	<6	5
91.	"	3	13	-	-	-	6	7
92.	"	2	11	-	-	-	6	8
93.	Rh Negative	3	8	13	-	IV Oxytocin	6	21
94.	"	2	4	8	-	"	12	22
95.	Post dated	3	3	5	5	"	FR	32
96.	"	2	8	11	13	"	6	32
97.	PET	2	8	10	13	"	6	26
98.	"	3	3	5	5	"	FP	32
99.	"	2	8	10	13	"	-	28
100.	"	2	9	10	13	"	6	26

	16	17	18	19	20
67.	-	-	-	9/10	-
68.	-	-	-	9/10	-
69.	-	-	FPI	9/10	H.B.
70.	-	-	-	9/10	-
71.	-	-	-	9/10	-
72.	-	-	PPH	9/10	-
73.	-	-	-	10/10	-
74.	-	-	-	10/10	-
75.	-	-	-	10/10	-
76.	-	-	-	9/10	-
77.	-	-	-	9/10	-
78.	-	-	-	9/10	-
79.	-	-	-	9/10	-
80.	-	-	-	8/10	-
81.	-	-	-	7/10	-
82.	-	-	-	10/10	-
83.	-	-	-	9/10	-
84.	-	-	Hyper pyrexia	9/10	-
85.	-	-	-	9/10	-
86.	-	-	-	9/10	-
87.	-	-	-	Dead baby	-
88.	-	-	-	"	-
89.	-	-	-	"	-
90.	-	-	-	"	-
91.	-	-	-	"	-
92.	-	-	-	"	-
93.	-	-	-	9/10	H.B.
94.	-	-	-	9/10	-
95.	CS	PF	-	-	-
96.	"	NPOL	-	8/10	-
97.	"	NpOL	-	9/10	-
98.	"	PP	-	9/10	-
99.	"	NPOL	-	8/10	-
100.	"	NPOL	-	9/10	-

MASTER CHART

Intravenous oxytocin group (Control group).

Sl. No.	Name	Age (yrs)	B.P.	Urine albumin	Parity	G.A. (weeks)
1	2	3	4	5	6	7
1.	Anju	18	130/84	-	Po	41
2.	Nirmala	22	124/84	-	Po	41
3.	Suman	18	110/84	-	Po	42
4.	Kamlesh	28	110/80	-	Po	42
5.	Rama Devi	23	110/60	-	Po	42
6.	Sangeeta	18	110/68	-	Po	41
7.	Heera Devi	27	120/88	-	Po	41
8.	Gayatri	27	124/88	-	Po	41
9.	Mithila	23	110/84	-	Po	42
10.	Imarti	23	110/84	-	Po	41
11.	Prabha	18	130/84	-	Po	41
12.	Kishori Devi	22	124/84	-	Po	41
13.	Shakila	18	110/84	-	Po	42
14.	Shahnaz	28	110/80	-	Po	42
15.	Kushma	23	110/60	-	Po	42
16.	Dhanwati	18	110/68	-	Po	41
17.	Sulekha	27	120/88	-	Po	41
18.	Rani	27	124/88	-	Po	41
19.	Geeta Devi	23	110/84	-	Po	42
20.	Savita	23	110/84	-	Po	41
21.	Narvada	23	160/110	1+	Po	39
22.	Pratima	20	170/110	-	Po	37
23.	Urmila	22	130/106	-	Po	38
24.	Malti	21	160/100	2+	Po	39
25.	Suman Lata	22	150/100	-	Po	38
26.	Janki	20	180/100	1+	Po	38
27.	Vandana	25	130/104	-	Po	38
28.	Vineeta	23	160/104	-	Po	39
29.	Girija	20	170/110	2+	Po	37
30.	Sahlee	22	130/104	-	Po	38
31.	Rekha	21	160/110	1+	Po	39

Sl. No.	Indication for induction	Bishop Score at PI	6H	12H	24H	I.P.I. (hours)	I.D.I. (hours)	Mode of delivery
	8	9	10	11	12	13	14	15
1.	Post dated	4	5	13	-	12	17	Vag.
2.	"	4	8	-	-	6	10	Vag.
3.	"	5	8	12	-	6	22	Vag.
4.	"	5	5	9	-	12	23	Vag.
5.	"	5	-	-	-	∠6	6	Vag.
6.	"	5	8	12	-	12	15	Vag.
7.	"	4	8	-	-	6	12	Vag.
8.	"	4	8	11	-	6	18	Vag.
9.	"	2	4	8	12	12	29	Vag.
10.	"	4	4	10	13	12	29	Vag.
11.	"	4	5	13	-	12	17	Vag.
12.	"	4	8	-	-	6	10	Vag.
13.	"	5	8	12	-	6	22	Vag.
14.	"	5	5	9	-	12	23	Vag.
15.	"	5	-	-	-	∠6	6	Vag.
16.	"	5	8	12	-	12	15	Vag.
17.	"	4	8	-	-	6	12	Vag.
18.	"	4	8	11	-	6	18	Vag.
19.	"	2	4	8	12	12	29	Vag. (F)
20.	"	4	4	10	13	12	29	Vag.
21.	PET	3	6	12	-	6	14	Vag.
22.	"	5	9	-	-	6	10	Vag.
23.	"	4	5	10	12	12	28	Vag.
24.	"	4	5	12	-	12	24	Vag.
25.	"	3	4	6	10	12	36	Vag.
26.	"	5	11	-	-	6	9	Vag.
27.	"	4	6	10	-	6	19	Vag.
28.	"	3	6	12	-	6	14	Vag.
29.	"	5	9	-	-	6	10	Vag.
30.	"	4	5	10	12	12	28	Vag.
31.	"	4	5	12	-	12	24	Vag.
32.	"	3	4	6	10	12	36	Vag.

Sl. No.	INDICATION for LSCS	Maternal Complications	APGAR at 5 minutes	Neonatal Complications
	16	17	18	19
1.	-	-	9/10	-
2.	-	-	9/10	-
3.	-	-	9/10	-
4.	-	-	9/10	-
5.	-	-	9/10	-
6.	-	-	8/10	-
7.	-	-	9/10	-
8.	-	-	9/10	-
9.	-	Hyper pyrexia	6/10	A.N.
10.	-	-	6/10	A.N.
11.	-	-	9/10	-
12.	-	-	8/10	-
13.	-	-	9/10	-
14.	-	-	9/10	-
15.	-	-	9/10	-
16.	-	-	9/10	-
17.	-	-	7/10	-
18.	-	-	8/10	-
19.	-	-	8/10	H.B.
20.	-	-	7/10	H.B.
21.	-	-	9/10	-
22.	-	-	9/10	-
23.	-	-	8/10	H.B.
24.	-	-	8/10	H.B.
25.	-	Hyper pyrexia	6/10	A.N.
26.	-	-	7/10	-
27.	-	-	8/10	-
28.	-	-	8/10	-
29.	-	-	9/10	-
30.	-	-	7/10	-
31.	-	-	8/10	-
32.	-	-	8/10	-
33.	-	-	9/10	-

1	2	3	4	5	6	7
32.	Manju	22	150/100	-	Po	38
33.	Rashida	20	180/100	-	Po	38
34.	Nootan	25	130/104	-	Po	38
35.	Durga	26	110/84	-	Po	41
36.	Hemlata	25	120/82	-	Po	42
37.	Munni	22	124/80	-	Po	41
38.	Reshma	21	120/84	-	Po	42
39.	Leela	20	120/88	-	Po	41
40.	Seema Gupta	20	120/84	-	Po	41
41.	Savitri	21	110/82	-	Po	42
42.	Shahin	25	106/84	-	Po	41
43.	Vandana	24	110/82	-	Po	42
44.	Guddi	19	110/84	-	Po	41
45.	Sangita	26	112/80	-	Po	42
46.	Jaishree	25	114/84	-	Po	41
47.	Indrani	22	112/80	-	Po	41
48.	Meena	21	110/84	-	Po	42
49.	Jayda	20	160/120	1+	Po	38
50.	Rekha	20	170/110	-	Po	39
51.	Ram Bai	21	160/100	2+	Po	37
52.	Bhagwati	25	150/110	-	Po	38
53.	Saroj	24	160/100	3+	Po	39
54.	Padma Kumari	19	160/110	-	Po	37
55.	Mamta	25	112/80	-	P_1	41
56.	Rekha Devi	24	114/84		P_2	41
57.	Pushpa	26	110/80	-	P_1	42
58.	Malti	25	120/84	-	P_1	42
59.	Mamta	25	124/80	-	P_2	41
60.	Sadhna	28	120/84	-	P_2	41
61.	Sandhya	29	110/80	-	P_2	42
62.	Usha	22	120/84	-	P_1	42
63.	Munni	25	124/80	-	P_1	41
64.	Savitri Devi	24	120/84	-	P_2	41
65.	Bhagwati	26	110/84	-	P_1	42
66.	Kiran	25	110/80	-	P_1	42

	8	9	10	11	12	13	14	15
33.	PET	5	11	-	-	6	9	Vag.
34.	"	4	6	10	-	6	19	Vag.
35.	Post dated	4	4	5	-	-	22	LSCS
36.	"	3	4	4	-	-	20	C.S.
37.	"	2	4	5	5	-	32	C.S.
38.	"	2	6	8	10	6	30	C.S.
39.	"	4	3	6		12	16	C.S.
40.	"	2	4	4	-	-	18	C.S.
41.	"	4	4	5	5	-	26	C.S.
42.	"	2	6	-	-	6	12	C.S.
43.	"	4	8	10	-	6	14	C.S.
44.	"	5	5	5	6	24	28	C.S.
45.	"	4	4	5	-	-	22	C.S.
46.	"	3	4	4	-	-	20	C.S.
47.	"	2	4	5	5	-	36	C.S.
48.	"	2	6	8	10	6	30	C.S.
49.	PET	4	3	6	-	12	16	C.S.
50.	"	2	4	4	-	-	18	C.S.
51.	"	4	4	5	5	-	20	C.S.
52.	"	2	6	-	-	6	12	C.S.
53.	"	4	8	10	-	6	14	C.S.
54.	"	5	5	5	6	24	28	C.S.
55.	Post dated	3	4	5	13	24	25	Vag.
56.	"	3	6	12	-	6	20	Vag.
57.	"	4	8	13	-	6	20	Vag.
58.	"	4	11	-	-	6	8	Vag.
59.	"	4	7	10	13	6	26	Vag.
60.	"	4	9	12	-	6	18	Vag.
61.	"	5	10	-	-	6	10	Vag.
62.	"	4	10	12	-	6	14	Vag.
63.	"	3	4	5	13	24	25	Vag.
64.	"	3	6	12	-	6	20	Vag.
65.	"	4	8	13	-	6	20	Vag.
66.	"	4	11	-	-	6	8	Vag.

	16	17	18	19
34.	-	-	7/10	-
35.	FD	Hypertonic uterine activity	6/10	A.N.
36.	FD	HYper pyrexia	8/10	-
37.	Failed	-	8/10	-
38.	NPOL	-	9/10	-
39.	FD	-	8/10	-
40.	FD	Hypertonic uterine activity	5/10	A.N.
41.	Failed	-	8/10	-
42.	FD	Hyper pyrexia	6/10	A.N.
43.	FD	-	7/10	-
44.	NPOL	-	9/10	-
45.	FD	-	8/10	A.N.
46.	FD	Hyper pyrexia	7/10	-
47.	Failed	-	8/10	-
48.	NPOL	-	8/10	-
49.	FD	-	8/10	-
50.	FD	Hyper pyrexia	6/10	A.N.
51.	Failed	-	7/10	-
52.	FD	H.U.A.	8/10	-
53.	FD	H.U.A.	8/10	-
54.	NPOL	-	8/10	-
55.	-	-	9/10	-
56.	-	-	8/10	-
57.	-	-	9/10	-
58.	-	-	8/10	-
59.	-	-	9/10	-
60.	-	-	9/10	-
61.	-	-	9/10	-
62.	-	-	8/10	-
63.	-	-	9/10	-
64.	-	-	8/10	-
65.	-	-	7/10	-
66.	-	-	9/10	-

1	2	3	4	5	6	7
67.	Saroj	25	120/86	-	P1	41
68.	Priti	28	124/84	-	P2	41
69.	Prabha	29	128/80	-	P2	42
70.	Rajni	22	124/86	-	P2	42
71.	Hazra	22	160/110	-	P1	37
72.	Rekha Devi	24	160/100	1+	P1	37
73.	Malini	21	160/100	-	P1	37
74.	Taitoon	28	160/110	-	P2	38
75.	Raj Kumari	22	170/110	2+	P1	37
76.	Sheela	24	140/100	-	P2	38
77.	Maya Devi	21	150/100	-	P1	37
78.	Dhanwanti	28	154/106	2+	P1	37
79.	Gyanwati	28	150/100	-	P1	39
80.	Kailashi	28	140/98	1+	P1	39
81.	Suman	20	120/84	-	P1	38
82.	Janki	20	110/80	-	P1	38
83.	Pushpa	20	120/84	-	P1	38
84.	Kala	28	120/80	-	P3	38
85.	Meena	20	110/70	-	P3	38
86.	Ahilya	28	110/60	-	P1	38
87.	Sajjo	30	110/64	-	P2	41
88.	Tafrunisha	25	120/68	-	P2	41
89.	Ram Pyari	23	124/68	-	P2	41
90.	Neelam	26	120/70	-	P1	42
91.	Sahdevi	35	110/70	-	P2	42
92.	Raj Kumari	20	120/80	-	P2	41
93.	Rati	22	110/80	-	P2	41
94.	Jayanti	30	120/88	-	P1	38
95.	Usha	25	180/100	2+	P1	39
96.	Chameli	23	170/100	-	P1	38
97.	Rajni	26	170/110	1+	p1	31
98.	Mamta	35	160/100	-	P1	31
99.	Neelam	20	160/110	2+	P2	32
100.	Kusum	22	150/100	-	P2	38

	8	9	10	11	12	13	14	15
67.	Post dated	4	7	10	13	6	26	Vag.
68.	"	4	9	12	-	6	18	Vag.
69.	"	5	10	-	-	6	10	Vag.
70.	"	4	10	12	-	6	14	Vag.
71.	PET	4	5	9	13	12	26	Vag.
72.	"	5	-	-	-	-	6	Vag.
73.	"	5	7	10	-	6	16	Vag.
74.	"	4	6	10	-	6	24	Vag.
75.	"	4	9	-	-	6	11	Vag.
76.	"	4	5	9	13	12	26	Vag.
77.	"	5	-	-	-	-	6	Vag.
78.	"	5	7	10	-	6	16	Vag.
79.	"	4	6	10	-	6	24	Vag.
80.	"	4	9	-	-	6	11	Vag.
81.	Rh Negative	5	8	12	-	12	14	Vag.
82.	"	5	8	12	-	12	14	-
83.	I.U.D.	4	12	-	-	6	9	Vag.
84.	"	4	9	-	-	6	11	Vag.
85.	"	4	12	-	-	6	8	Vag.
86.	"	4	9	-	-	6	12	Vag.
87.	Post dated	2	5	-	-	-	11	LSCS
88.	"	2	4	6	-	12	14	C.S.
89.	"	4	5	5	-	-	13	C.S.
90.	"	4	4	5	5	-	30	C.S.
91.	"	2	5	-	-	-	8	C.S.
92.	"	2	4	6	-	12	14	C.S.
93.	"	4	5	5	-	-	22	C.S.
94.	PET	4	4	5	5	-	30	C.S.
95.	"	3	4	5	7	24	28	C.S.
96.	"	4	4	6	-	12	13	C.S.
97.	"	3	4	6	-	12	23	C.S.
98.	"	3	4	6	-	12	17	C.S.
99.	"	4	4	6	-	12	13	C.S.
100.	"	3	4	5	7	24	28	C.S.

	16	17	18	19
67.	-	-	8/10	-
68.	-	-	8/10	-
69.	-	-	9/10	-
70.	-	-	9/10	-
71.	-	Hyper pyrexia	6/10	A.N.
72.	-	-	9/10	-
73.	-	-	8/10	-
74.	-	-	8/10	-
75.	-	-	9/10	-
76.	-	-	7/10	H.B.
77.	-	-	9/10	-
78.	-	-	8/10	-
79.	-	-	8/10	-
80.	-	-	8/10	-
81.	-	-	8/10	H.B.
82.	-	-	7/10	-
83.	-	-	Dead Baby	-
84.	-	-	"	-
85.	-	-	"	-
86.	-	-	"	-
87.	FD	Hyper pyrexia	7/10	-
88.	FD		7/10	-
89.	FD	H.U.A.	6/10	A.N.
90.	Failed Ind.	-	7/10	-
91.	FD	Hyper pyrexia	8/10	-
92.	FD	H.U.A.	6/10	A.N.
93.	NPOL	-	8/10	-
94.	Failed Ind.	-	8/10	-
95.	NPOL	-	8/10	-
96.	FD	H.U.A.	6/10	A.N.
97.	NPOL	-	7/10	-
98.	FD	H.U.A.	7/10	-
99.	FD	Hyper pyrexia	8/10	-
100.	NPOL	-	8/10	-

APPENDIX - II

WORKING PROFORMA

COMPARATIVE STUDY OF ENDOCERVICAL APPLICATION OF PGE_2 GEL COMBINED WITH EARLY INTRAVENOUS INFUSION OF OXYTOCIN AND OXYTOCIN ALONE FOR INDUCTION OF LABOUR AT TERM IN PATIENTS WITH UNFAVOURABLE CERVIX

Sl.No._____ MRD No. _____

Date and Time of admission :

Name Age

Name of Husband

Address

COMPLAINTS

OBSTETRIC HISTORY

MENSTRUAL HISTORY

LMP

EDD

PAST AND PERSONAL HISTORY

Any other relevant point :

GENERAL EXAMINATION

Pulse Oedema

B.P. Weight

Pallor Jaundice

SYSTEMIC EXAMINATION

OBSTETRIC EXAMINATION

Per Abdomen :

Per Vaginal :

Per speculum:

INVESTIGATIONS

Blood : Hb gm%

Blood grouping & cross matching

Urine : Albumin: Sugar :

Ultrasonography (if done/required) :

INDICATION FOR INDUCTION :

DATE AND TIME FOR INDUCTION:

BISHOP SCORE

a. Before the start of medication.

b. At 6 hrs (if the patient has not delivered)

c. At 12 hours(if the patient has not delivered)

d. At 24 hours(if the patient has not delivered)

Instillation ripening interval :

Induction or augmentation of labour with oxytocin in patients with endocervical gel.

Induction delivery intervals (hrs) :

Failed ripening :

Failed induction :

Date and time of delivery :

Mode of delivery: Normal/Instrumental/Caesarean

Adverse reactions :

NEWBORN

APGAR Score : at 1 min.
at 5 min.

Any neonatal complications :
Predelivery -
Post delivery -

Maternal complications :
Pre delivery -
post delivery-

APPENDIX - III

A B B R E V I A T I O N S

Sl. No.	: Serial Number
B.S.	: Bishop Score
GA in wks	: Gestational age in weeks.
PIBS	: Pre-induction Bishop Score
IPI	: Induction priming interval.
IDI	: Induction Delivery Interval.
Hrs	: Hours
PDP	: Postdated pregnancy.
PIH	: Pregnancy Induced Hypertension.
FP	: Failed priming.
Failed Ind.	: Failed Induction.
NPOL	: Non progress of labour
Vag.	: Vaginal
C.S.	: Caesarean section.
V(F)	: Vaginal (Forceps)
PPH	: Postpartum haemorrhage
AN	: Asphyxia neonatorum
HUA	: Hypertonic uterine activity.
HB	: Hyperbilirubinaemia.
Mat Comp	: Maternal complications.
Neo Comp	: Neonatal complications.
AS 5	: APGAR Score at 5 minutes.
Cong. Ano.	: Congenital anomalies.
ND	: Neonatal death.